US009352124B2

(12) **United States Patent**
Hutchins et al.

(10) **Patent No.: US 9,352,124 B2**
(45) **Date of Patent: May 31, 2016**

(54) **METHOD OF AND APPARATUS FOR POSITIONING AND MAINTAINING THE POSITION OF ENDOSCOPIC INSTRUMENTS**

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(73) Assignee: **BOSTON SCIENTIFIC SCIMED, INC.**, Maple Grove, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 270 days.

(21) Appl. No.: **14/078,037**

(22) Filed: **Nov. 12, 2013**

(65) **Prior Publication Data**

US 2014/0058426 A1 Feb. 27, 2014

Related U.S. Application Data

(63) Continuation of application No. 13/561,183, filed on Jul. 30, 2012, now Pat. No. 8,579,895, which is a continuation of application No. 12/639,709, filed on Dec. 16, 2009, now Pat. No. 8,231,621, which is a

(Continued)

(51) **Int. Cl.**

A61B 18/18	(2006.01)
A61B 17/32	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61M 25/0136*** (2013.01); ***A61B 17/320016*** (2013.01); ***A61B 18/1492*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61M 25/0136; A61B 17/320016; A61B 18/1492; A61B 2017/22038; A61B 2218/002; A61B 2018/1407; A61B 2018/144; A61B 2018/1253; A61B 2018/00535; A61B 2017/22067; A61B 2018/1861; A61B 2018/00553; A61B 2017/003

See application file for complete search history.

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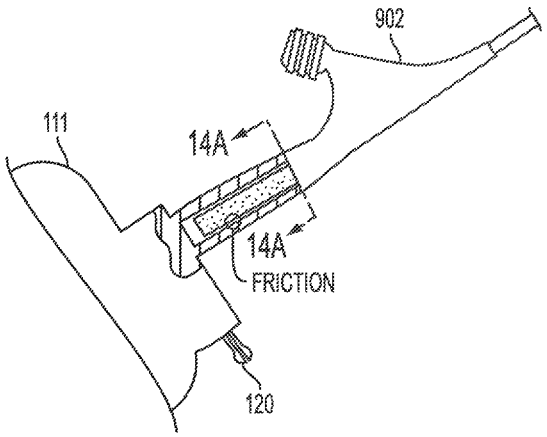
Primary Examiner — Julian W Woo

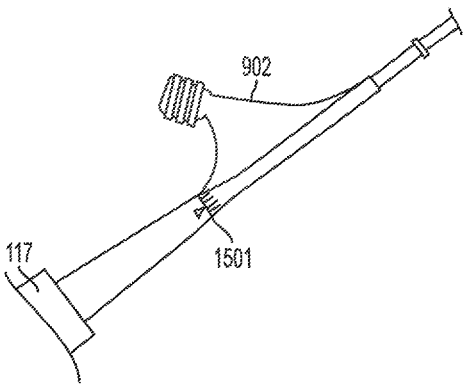
(74) *Attorney, Agent, or Firm* — Seager, Tufte & Wickhem, LLP

(57) **ABSTRACT**

The present invention provides an apparatus for, and a method of, accurate positioning of endoscopic instruments. Accurate positioning of the instruments is accomplished through the inclusion of a steering ability within the device. After the endoscopic instrument is properly positioned, the present invention may use rapid exchange technology, soft locks, and mechanical locks to maintain the position of the endoscopic instrument. Rapid exchange technology is used to minimize displacement forces present on the guidewire or catheters. Soft locks and mechanical locks resist movements caused by displacement forces.

16 Claims, 35 Drawing Sheets





Related U.S. Application Data

continuation of application No. 10/991,477, filed on Nov. 19, 2004, now Pat. No. 7,635,363, which is a continuation of application No. 10/003,678, filed on Dec. 6, 2001, now Pat. No. 6,827,718, which is a continuation-in-part of application No. 09/928,655, filed on Aug. 14, 2001, now Pat. No. 6,676,659.

(51) **Int. Cl.**

A61B 17/20	(2006.01)
A61M 25/01	(2006.01)
A61B 18/14	(2006.01)
A61B 17/00	(2006.01)
A61B 17/22	(2006.01)
A61B 18/00	(2006.01)
A61B 18/12	(2006.01)

(52) **U.S. Cl.**

CPC . *A61B2017/003* (2013.01); *A61B 2017/22038* (2013.01); *A61B 2017/22067* (2013.01); *A61B 2018/00535* (2013.01); *A61B 2018/00553* (2013.01); *A61B 2018/1253* (2013.01); *A61B 2018/144* (2013.01); *A61B 2018/1407* (2013.01); *A61B 2018/1861* (2013.01); *A61B 2218/002* (2013.01)

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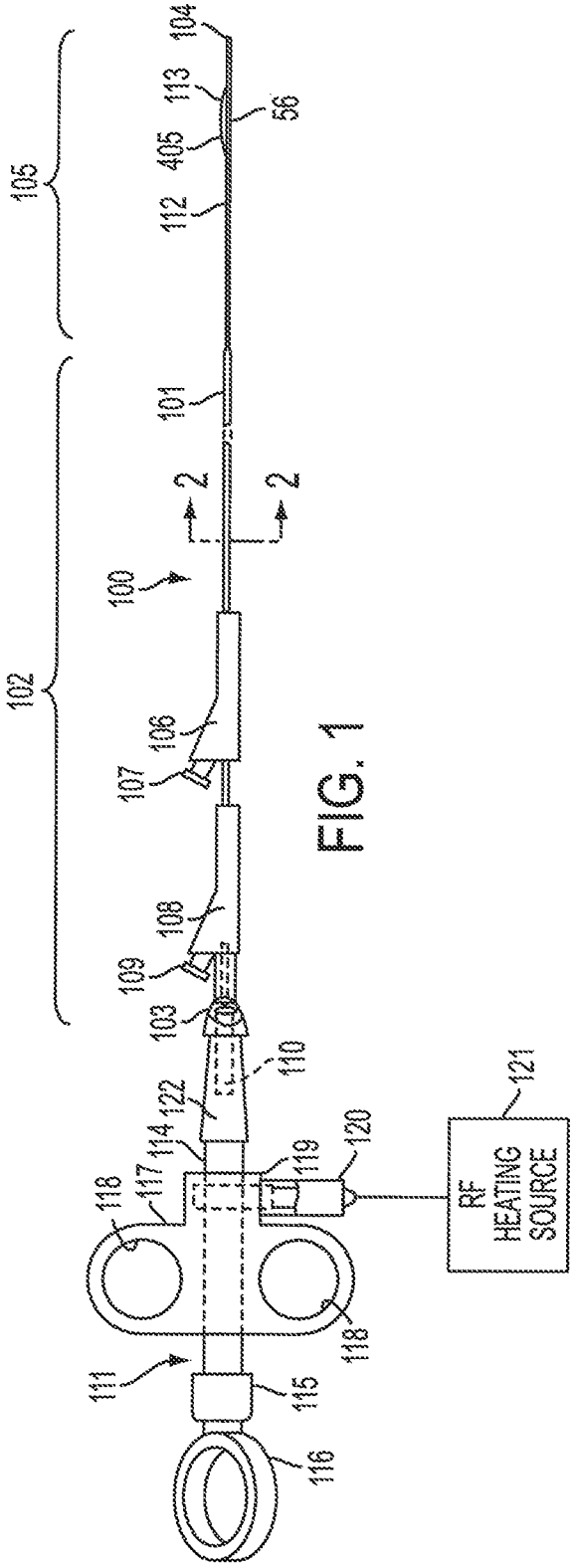
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FIG. 1

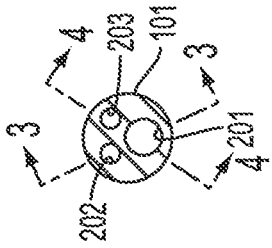
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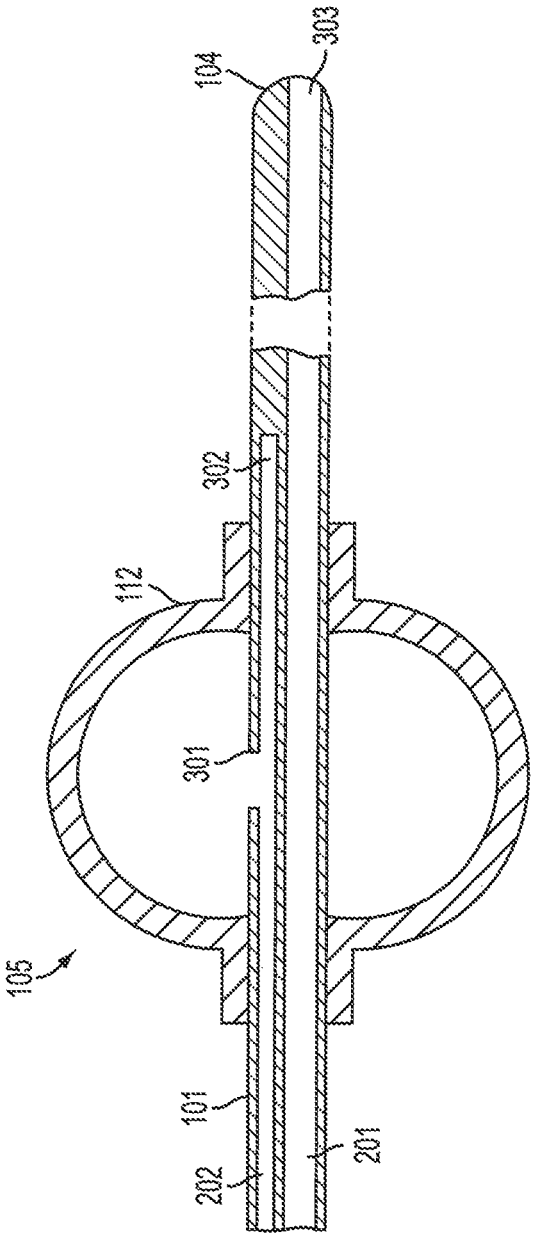
FIG. 2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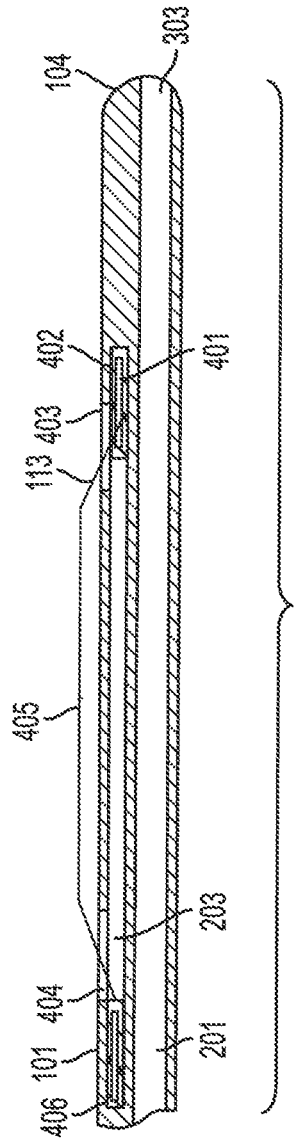
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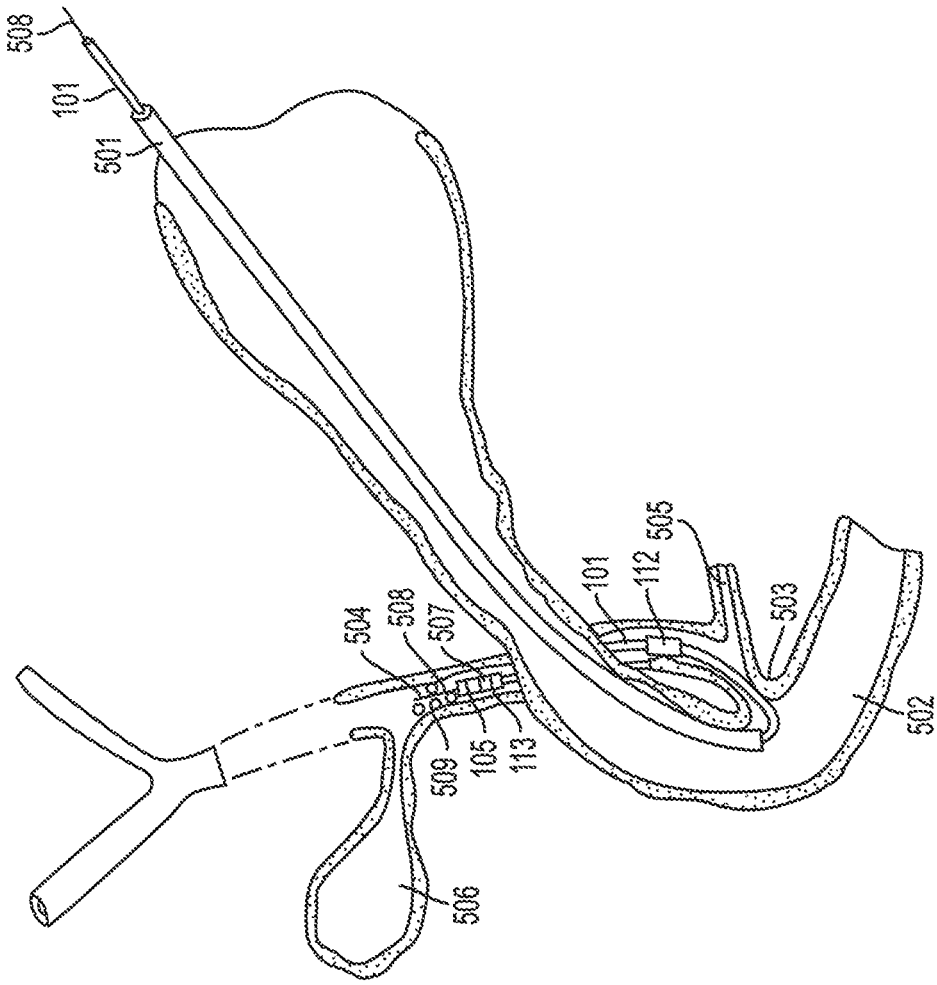

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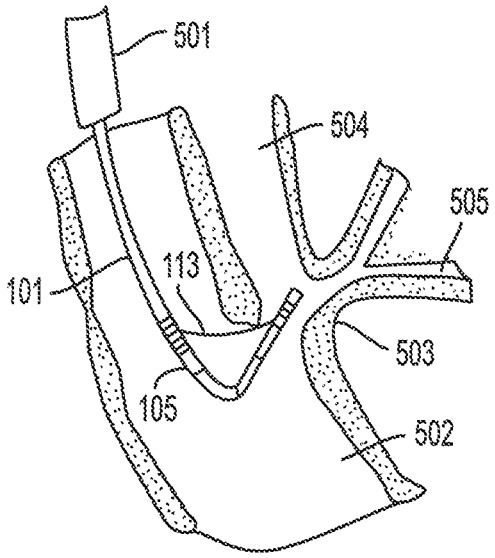
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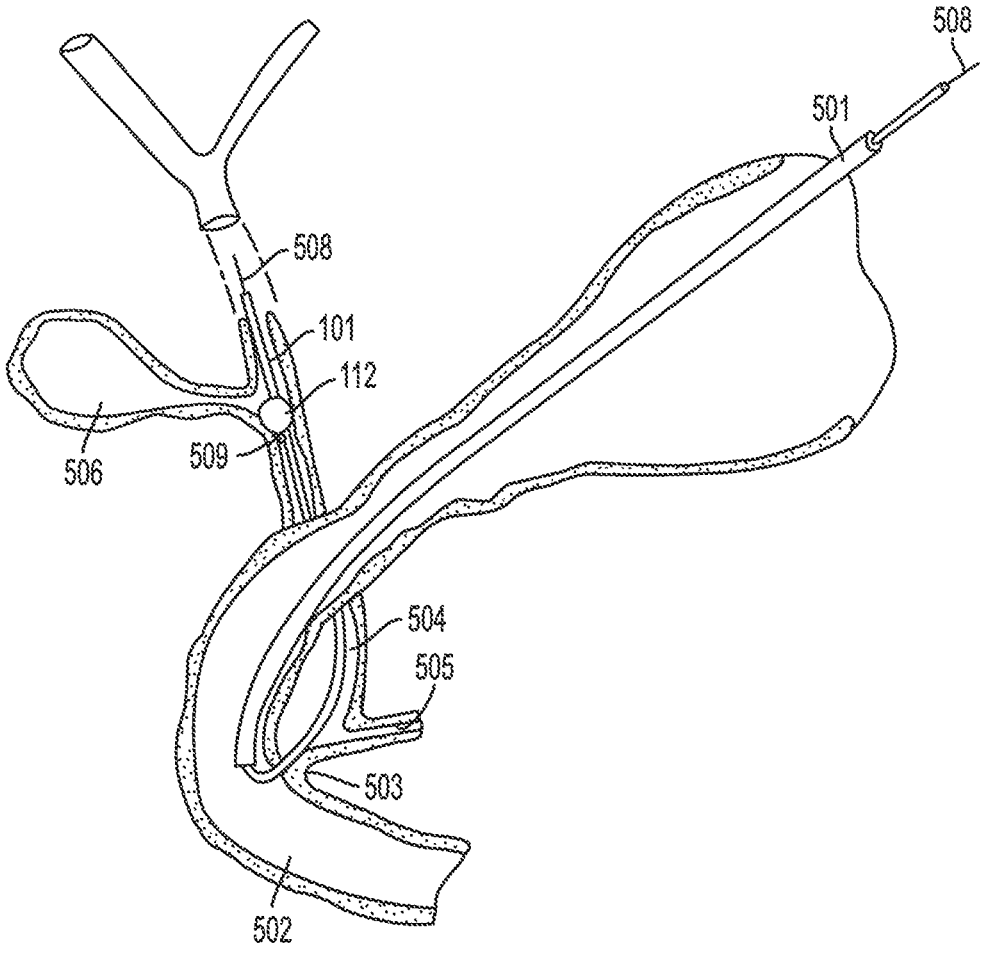
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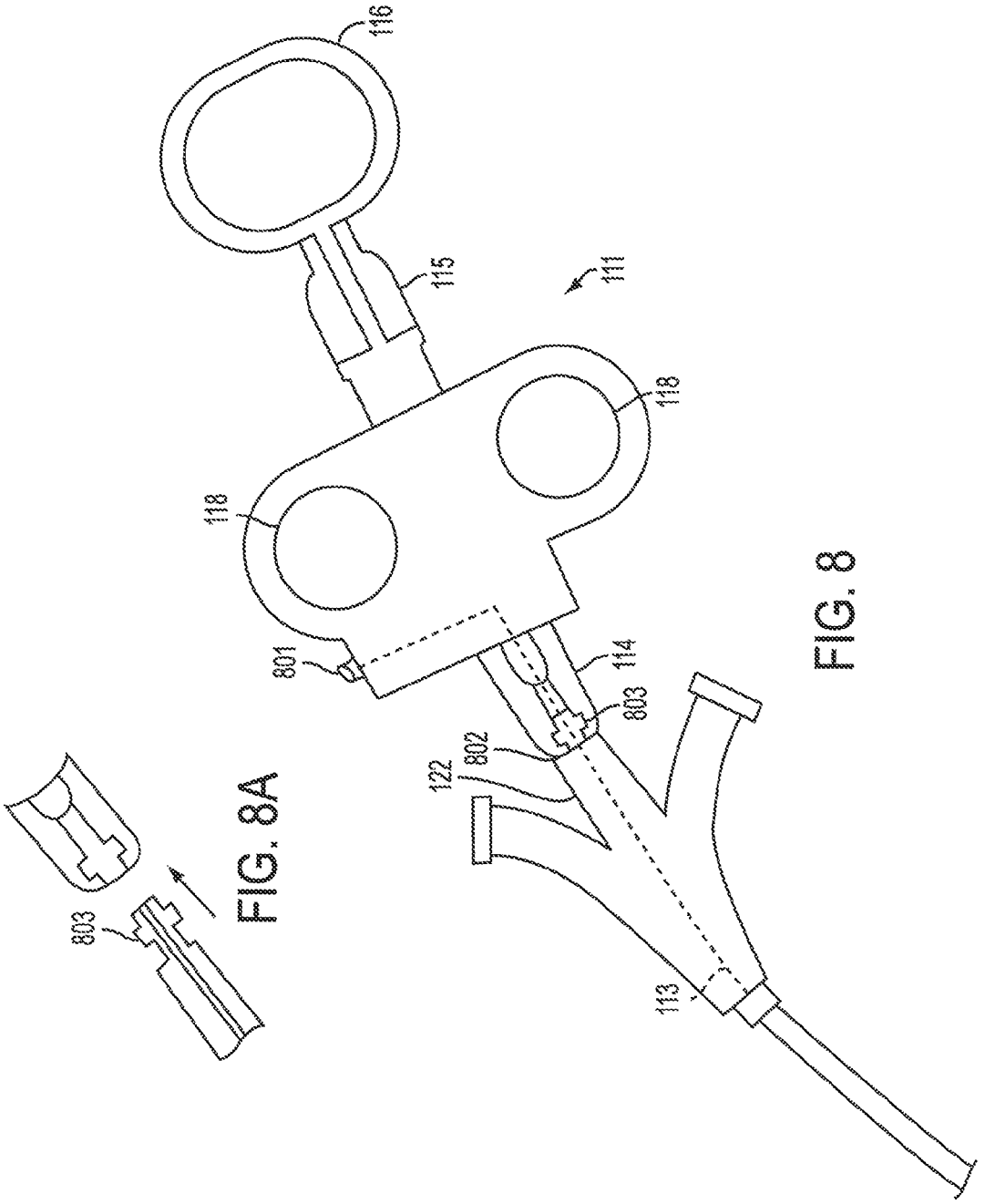
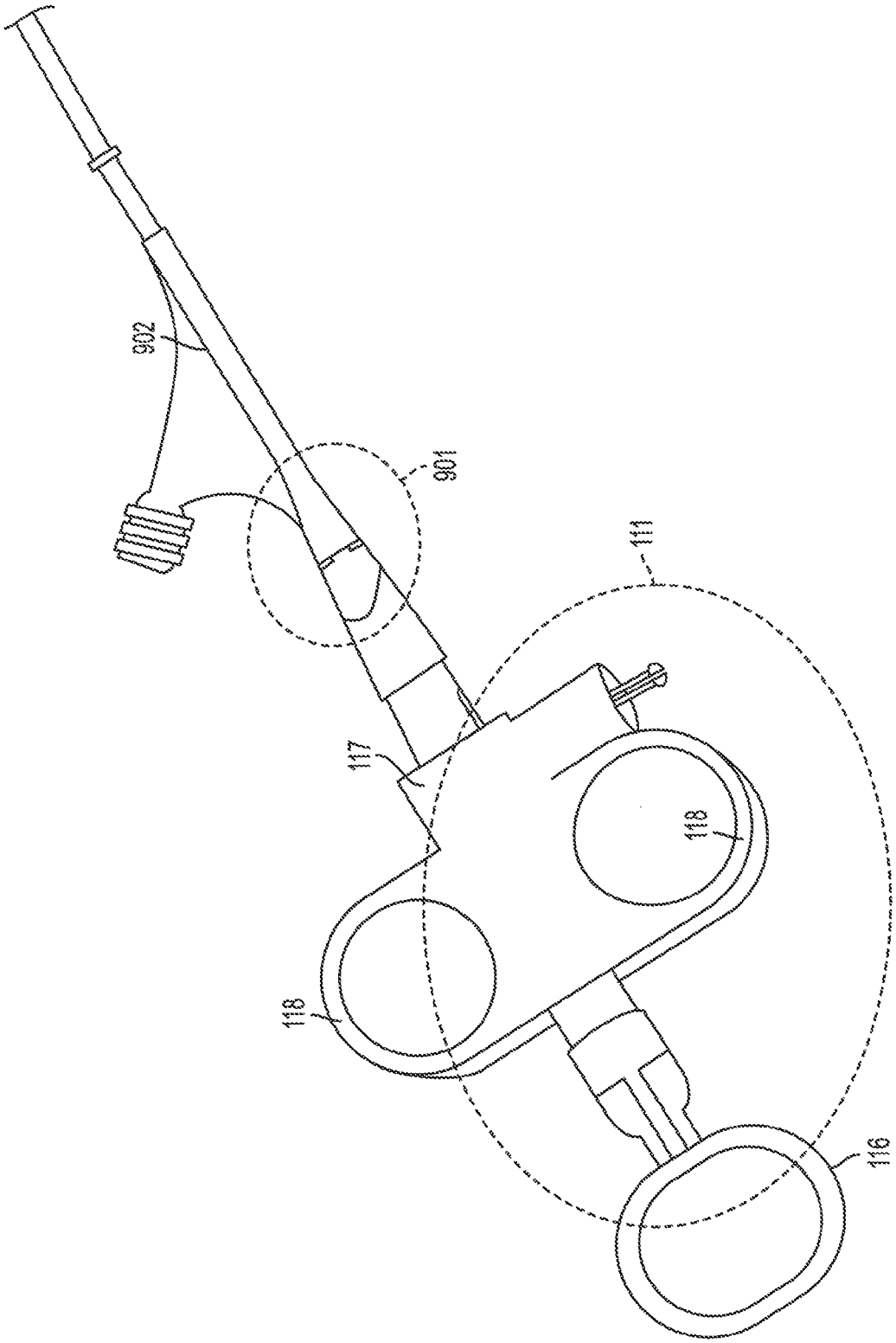


FIG. 8

FIG. 8A



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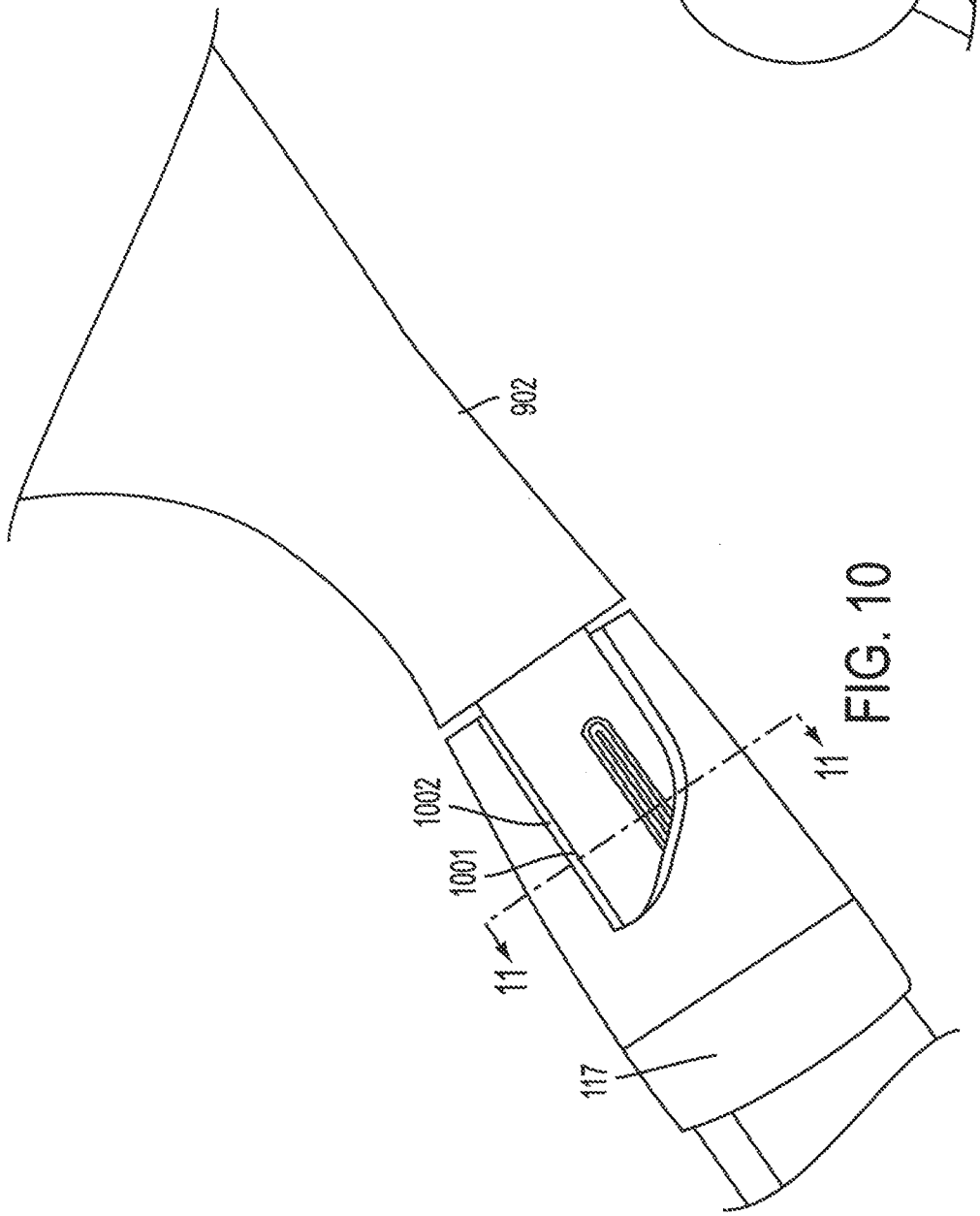
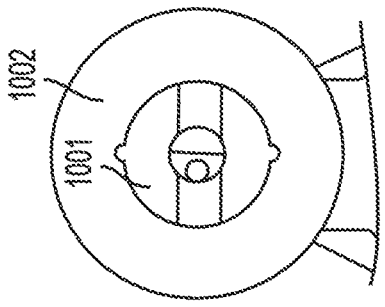


FIG. 10



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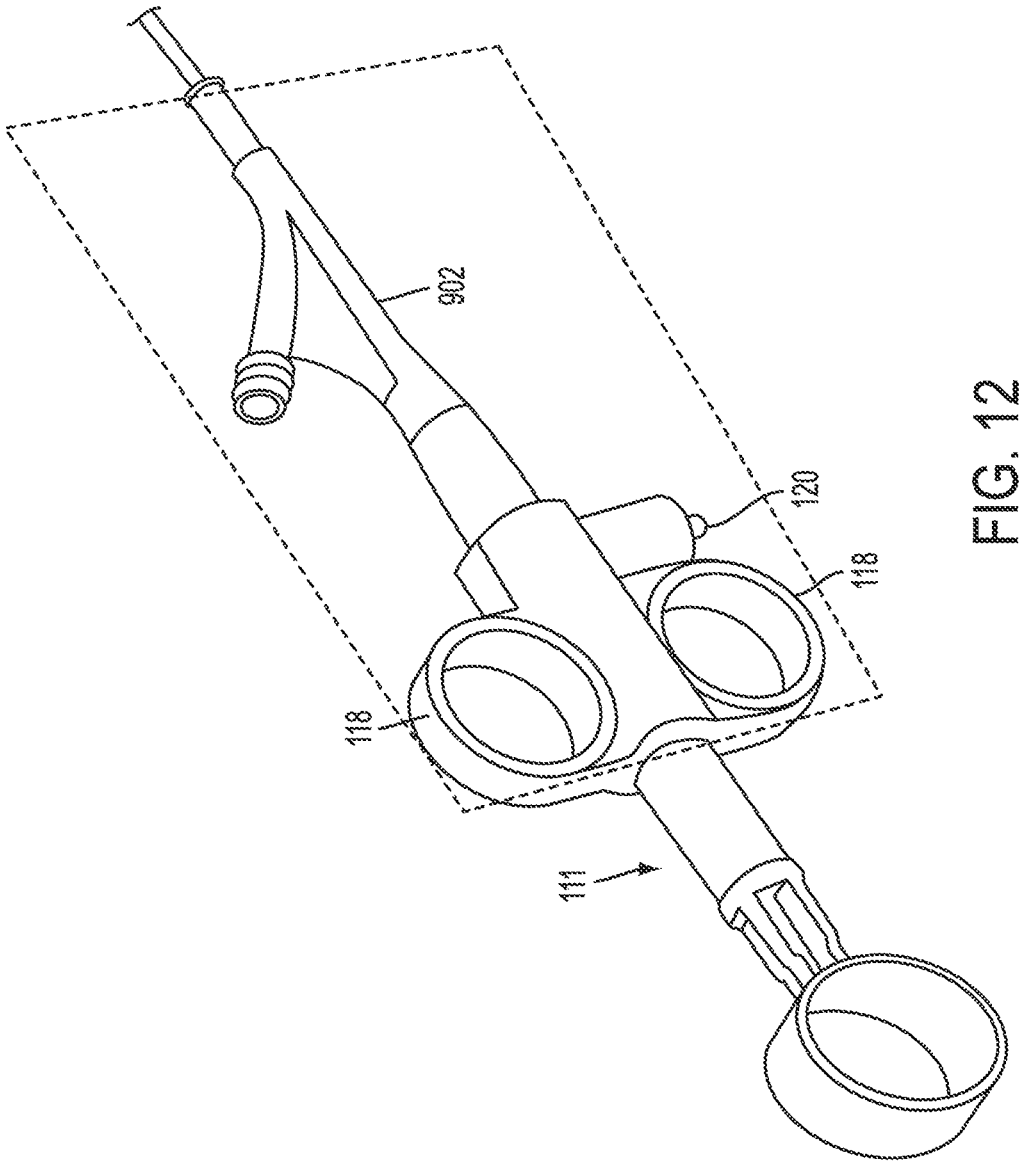

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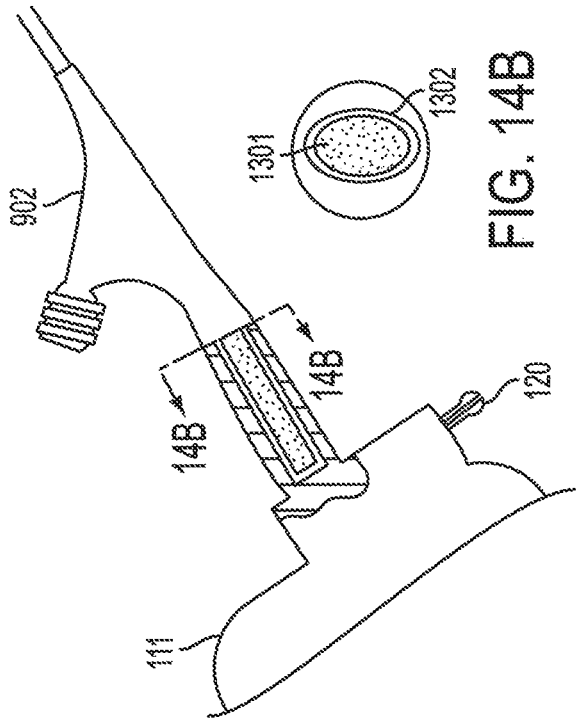


FIG. 13B

FIG. 14B

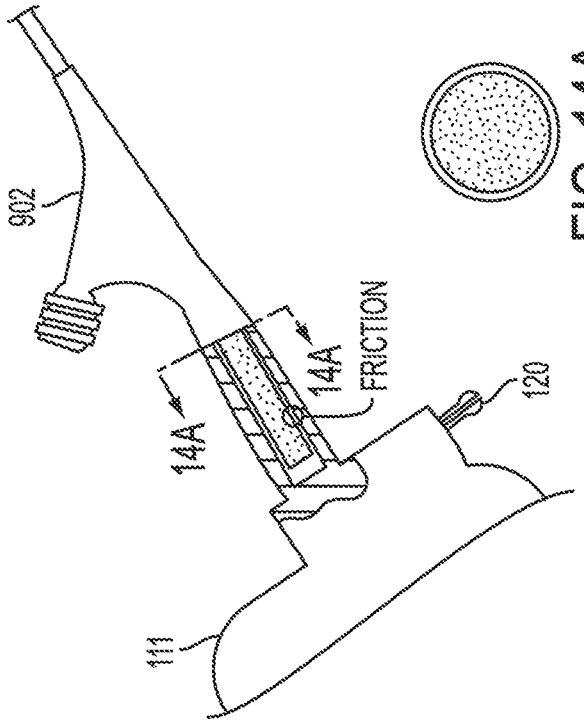


FIG. 13A

FIG. 14A

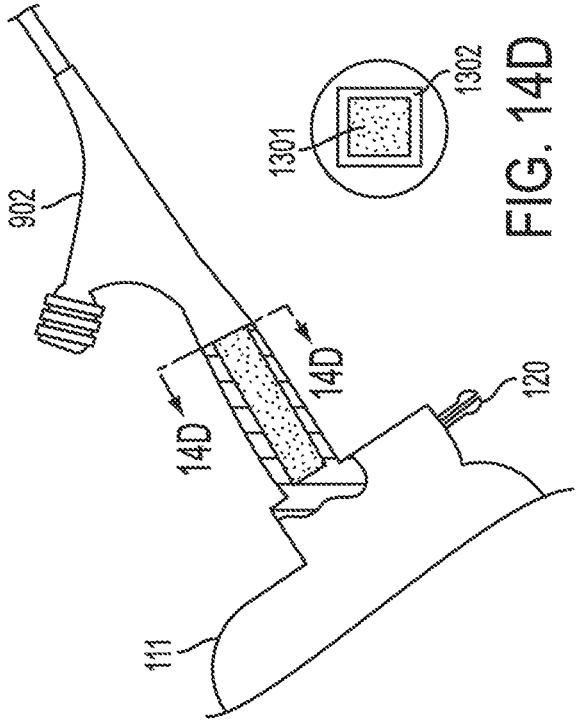


FIG. 13D

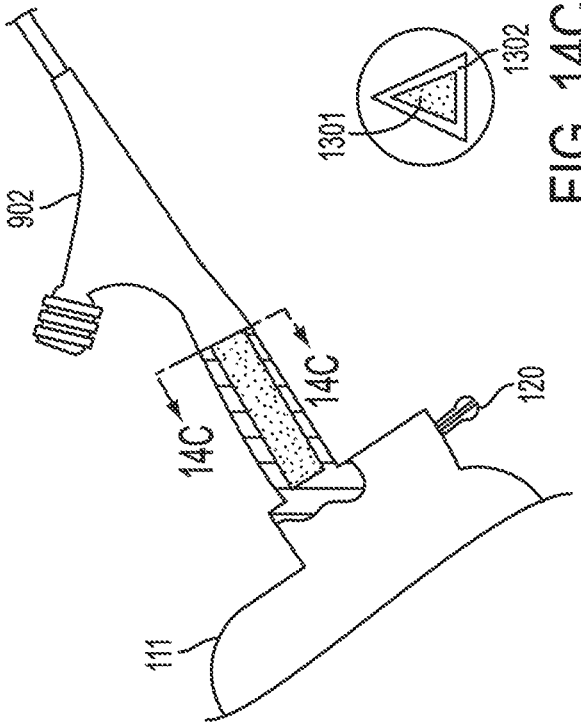


FIG. 13C

FIG. 14D

FIG. 14C

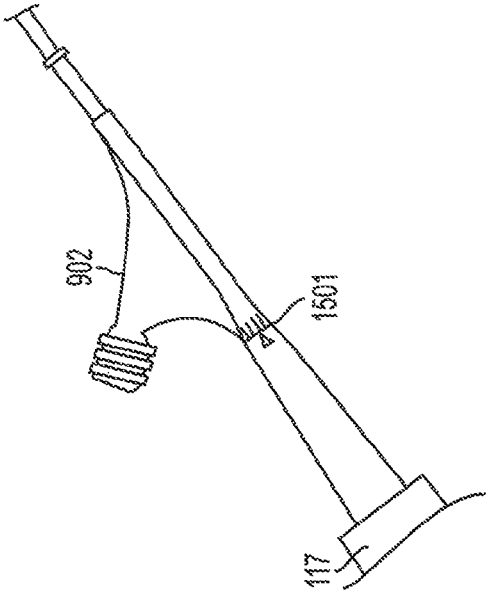


FIG. 15A

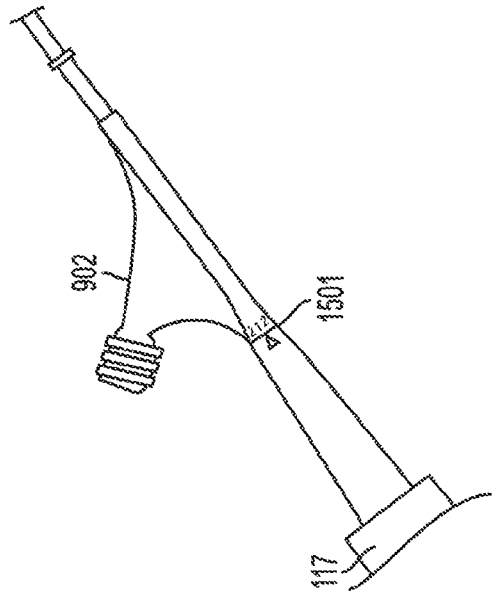


FIG. 15C

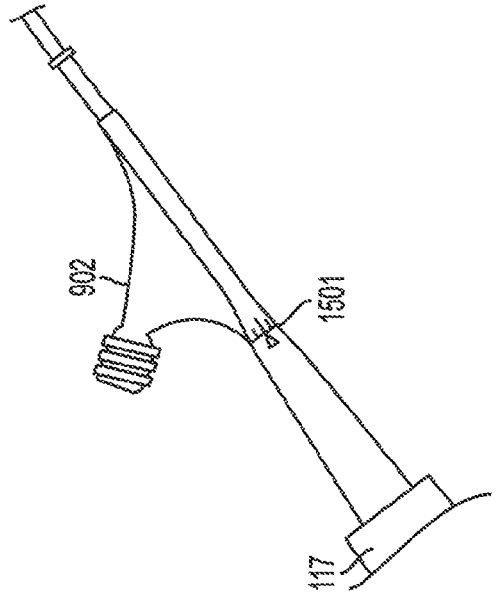


FIG. 15B

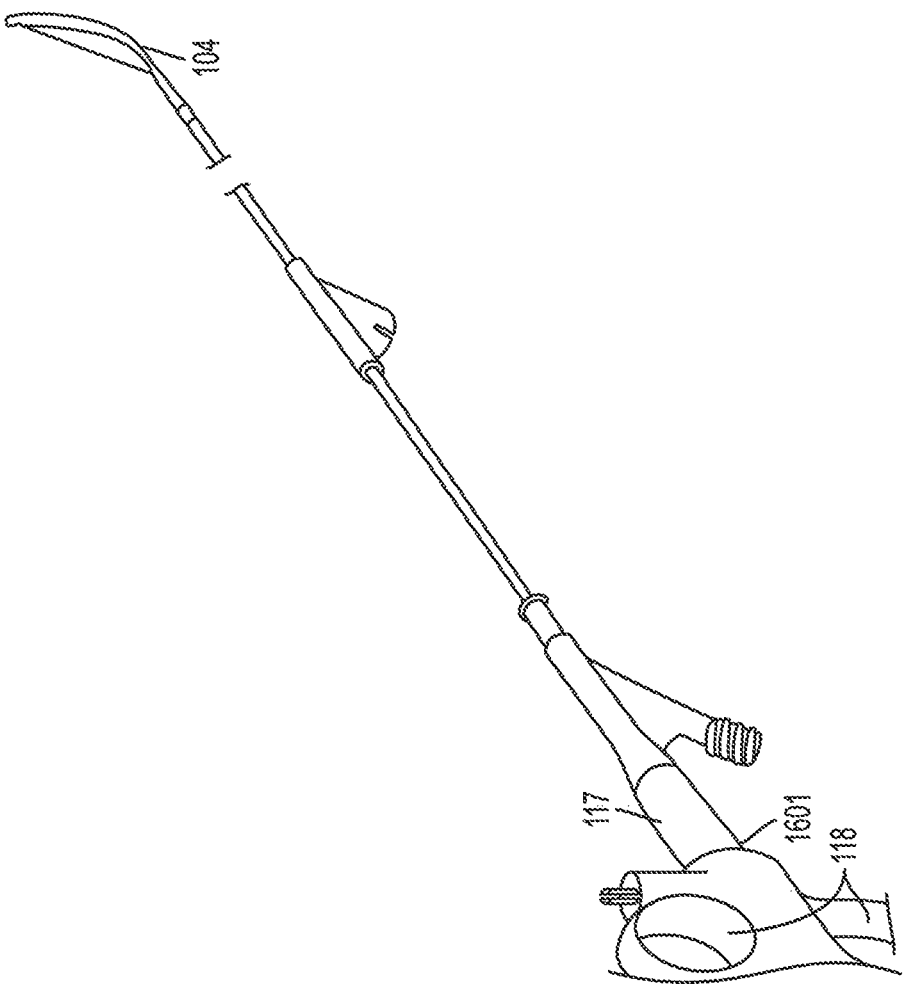


FIG. 16A

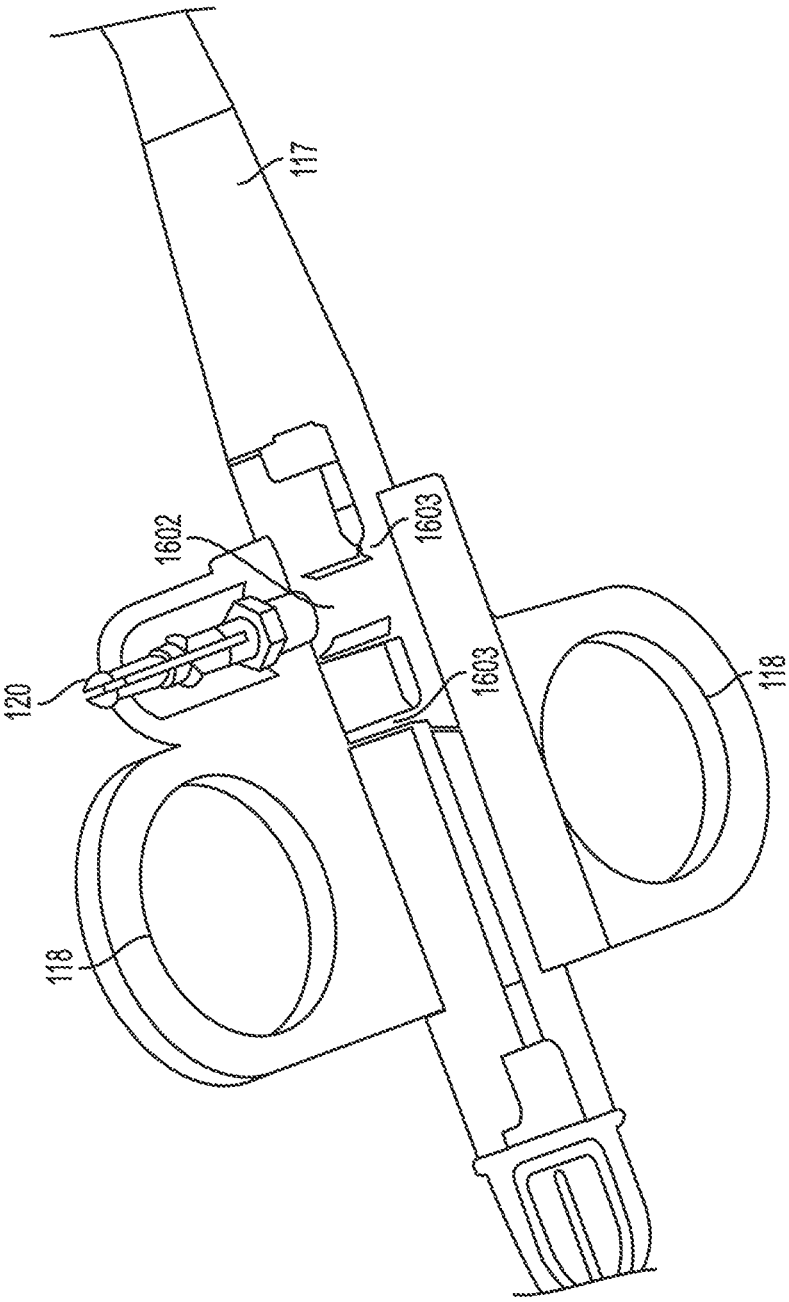
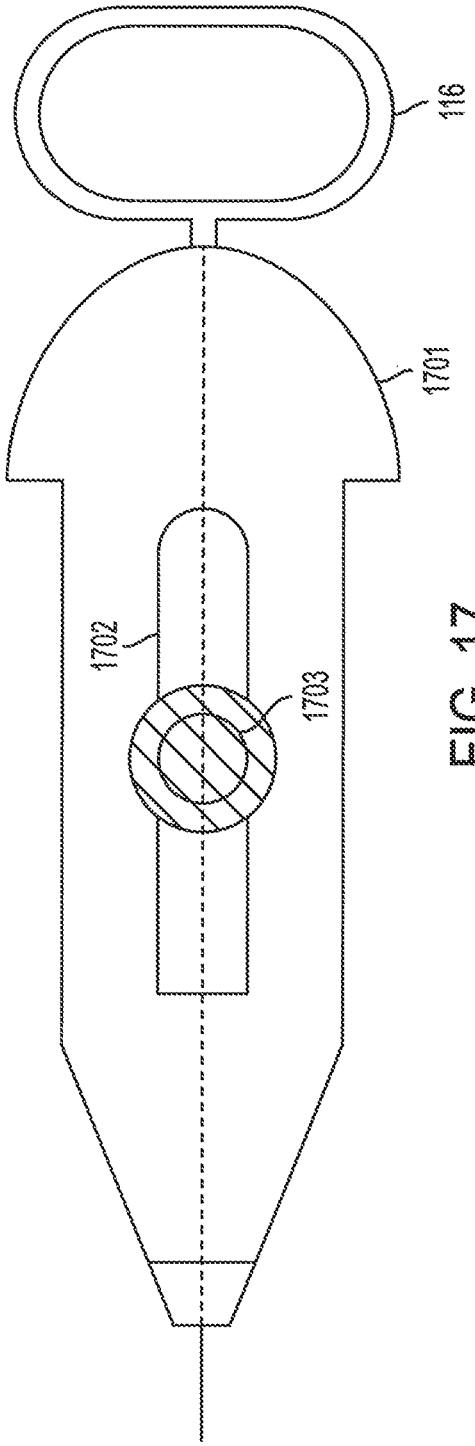


FIG. 16B



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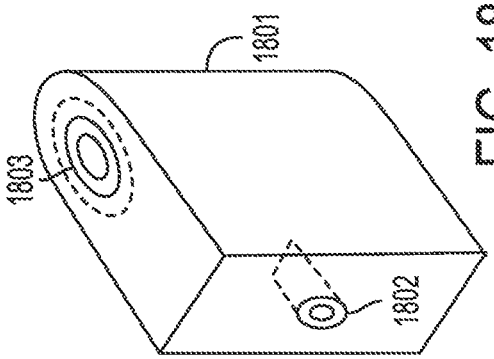

FIG. 18

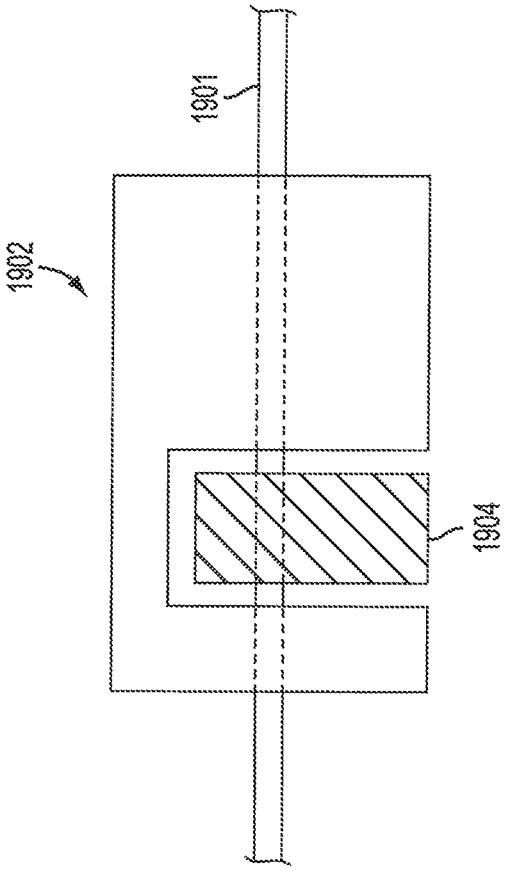

FIG. 19B

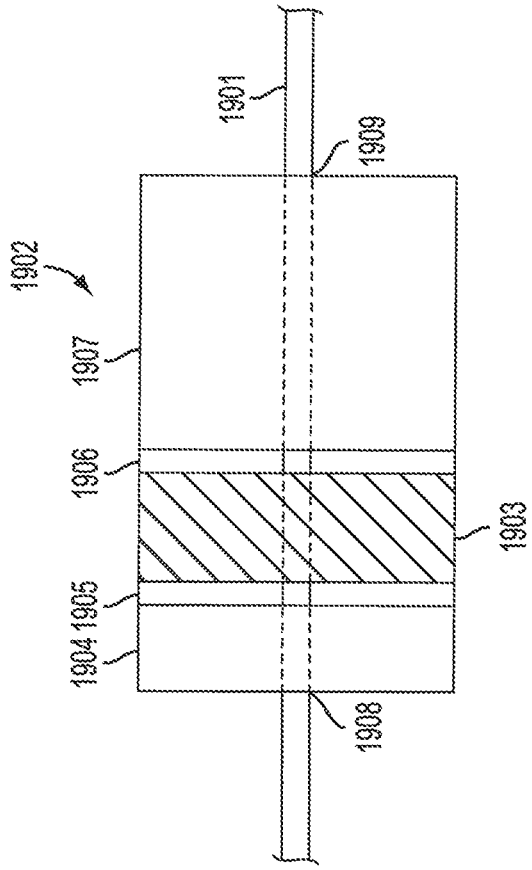

FIG. 19A

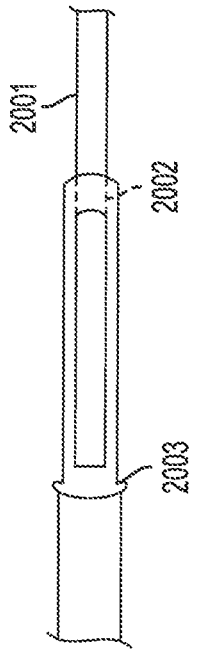

FIG. 20

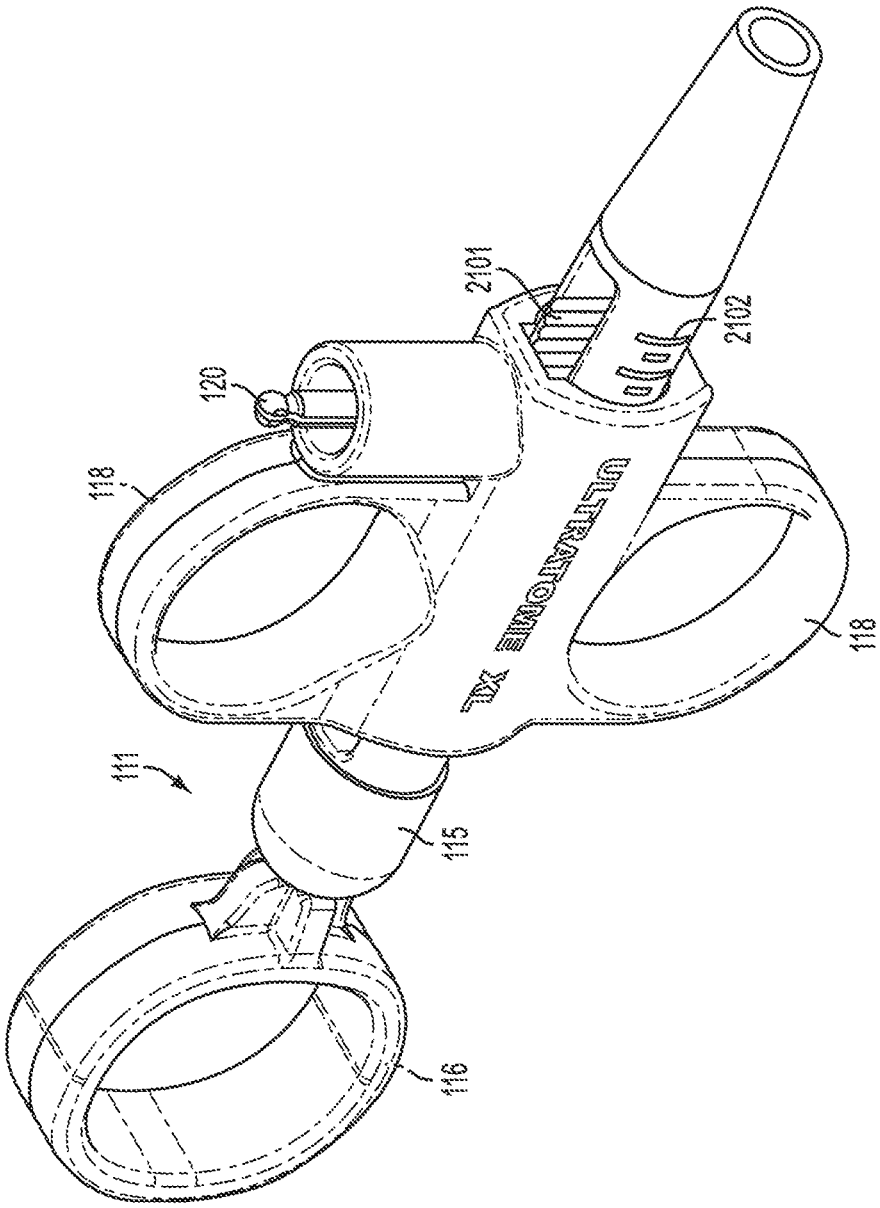

FIG. 21

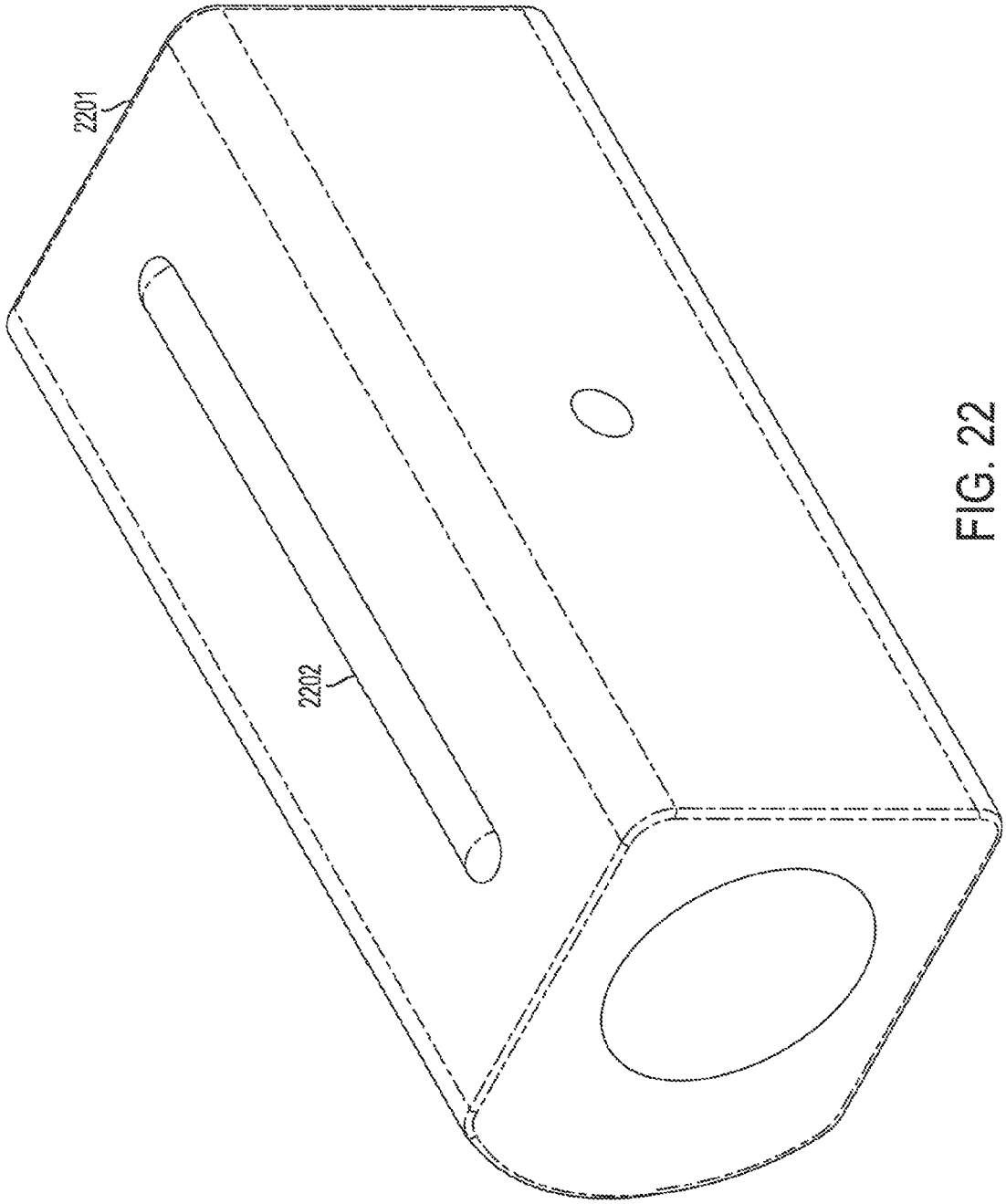

FIG. 22

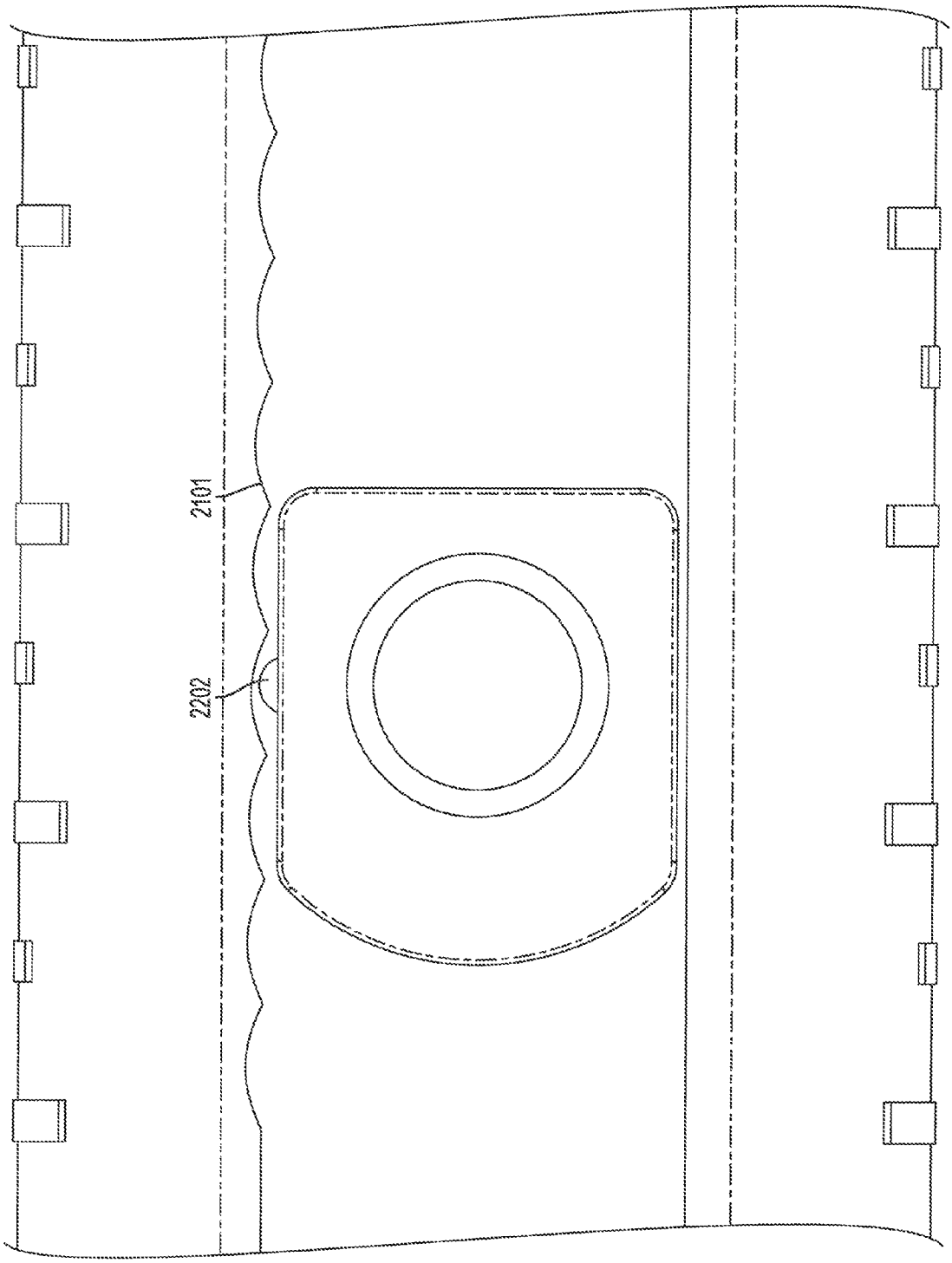

FIG. 23

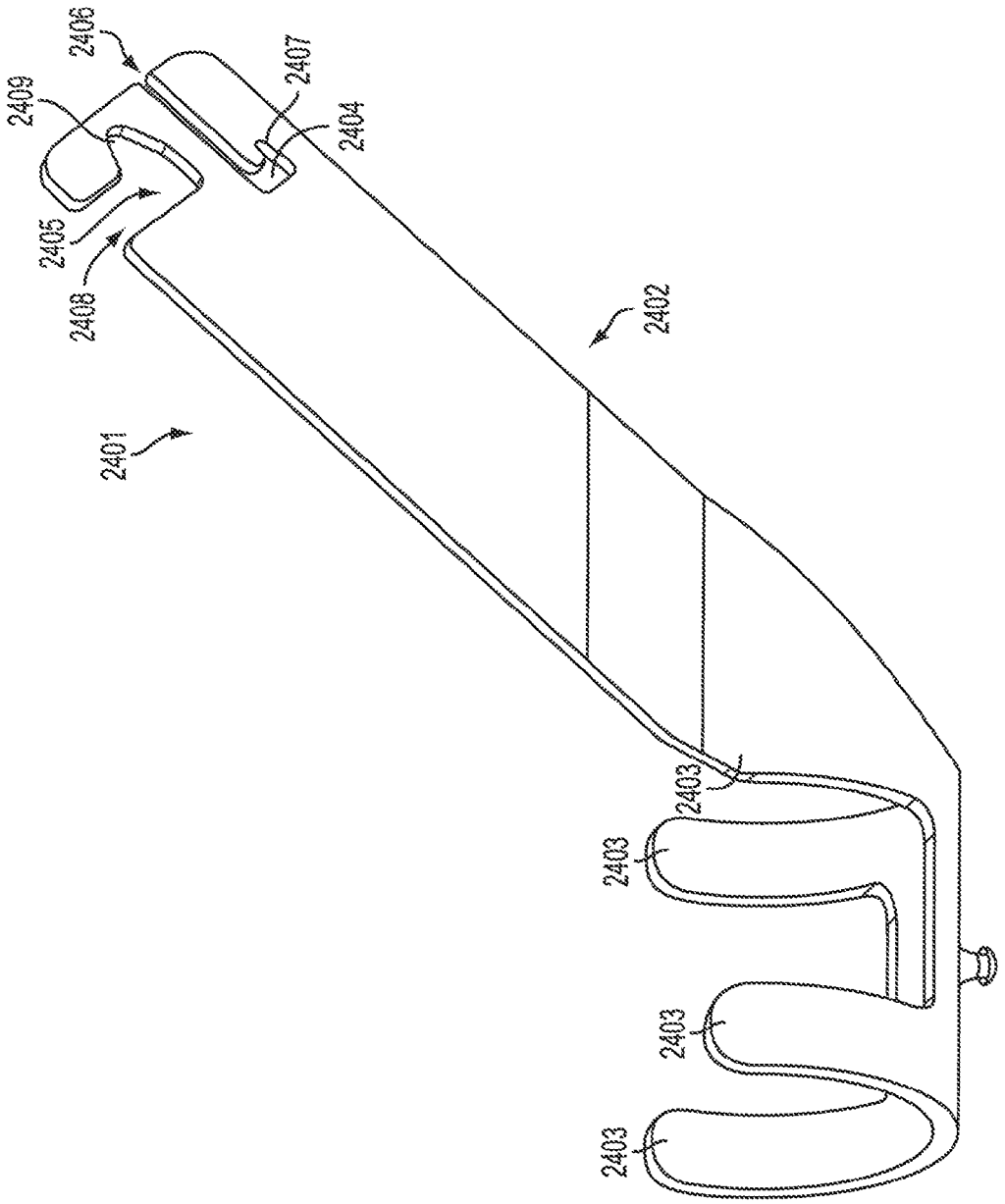

FIG. 24

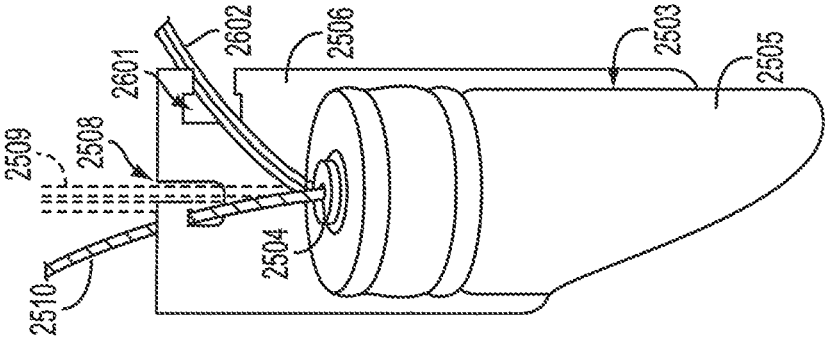
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FIG. 26

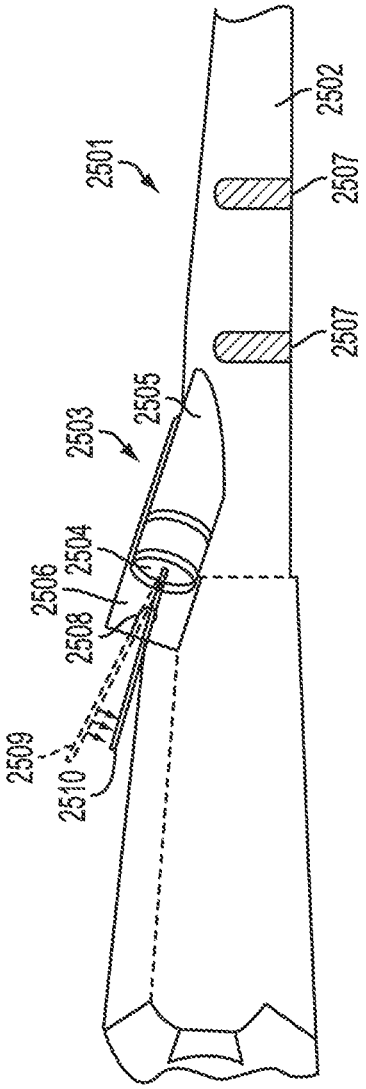
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FIG. 25

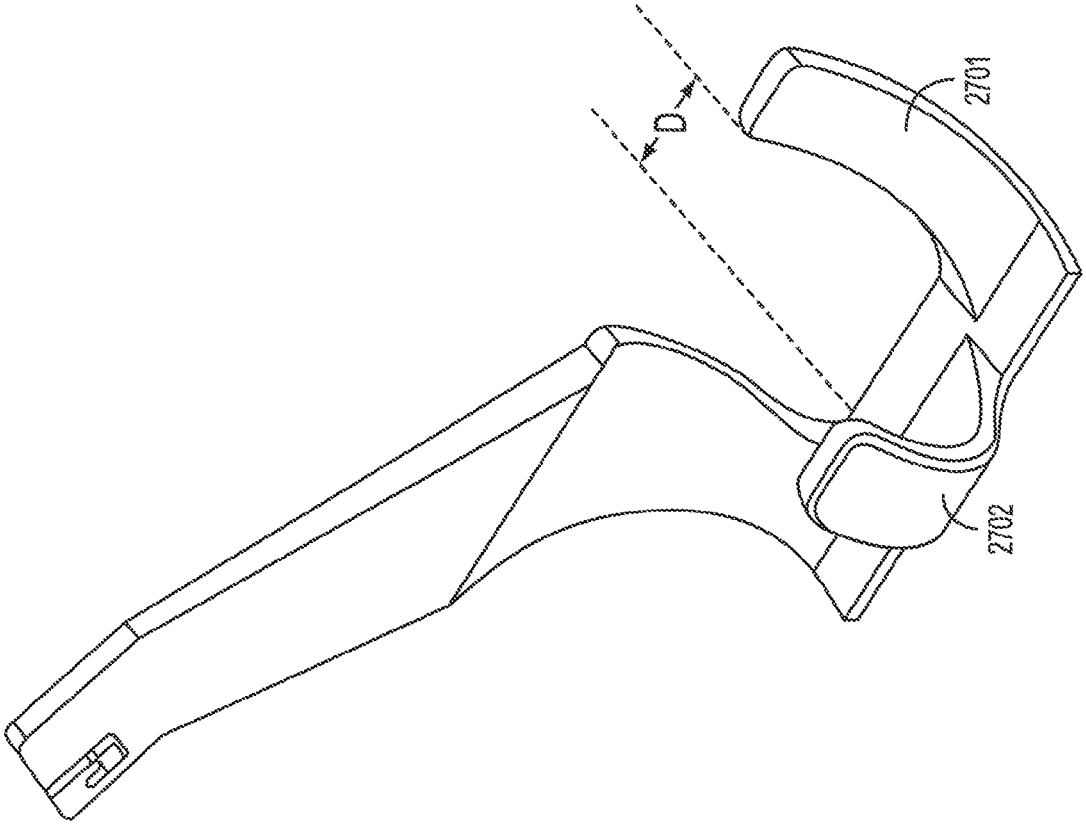

FIG. 27

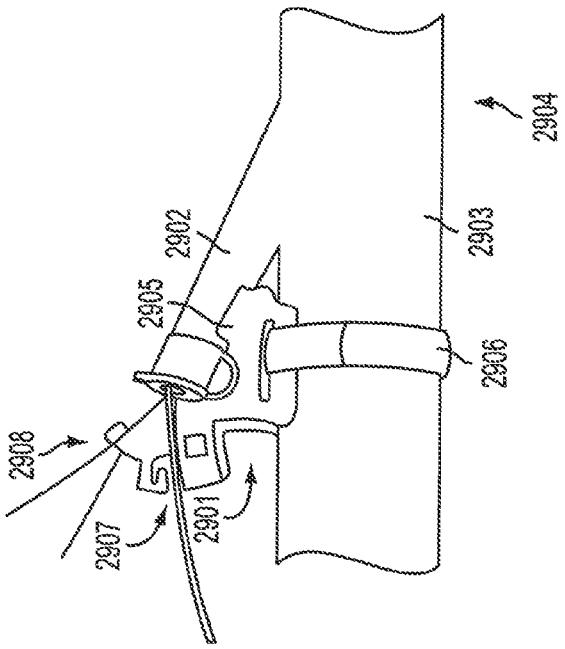
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FIG. 29

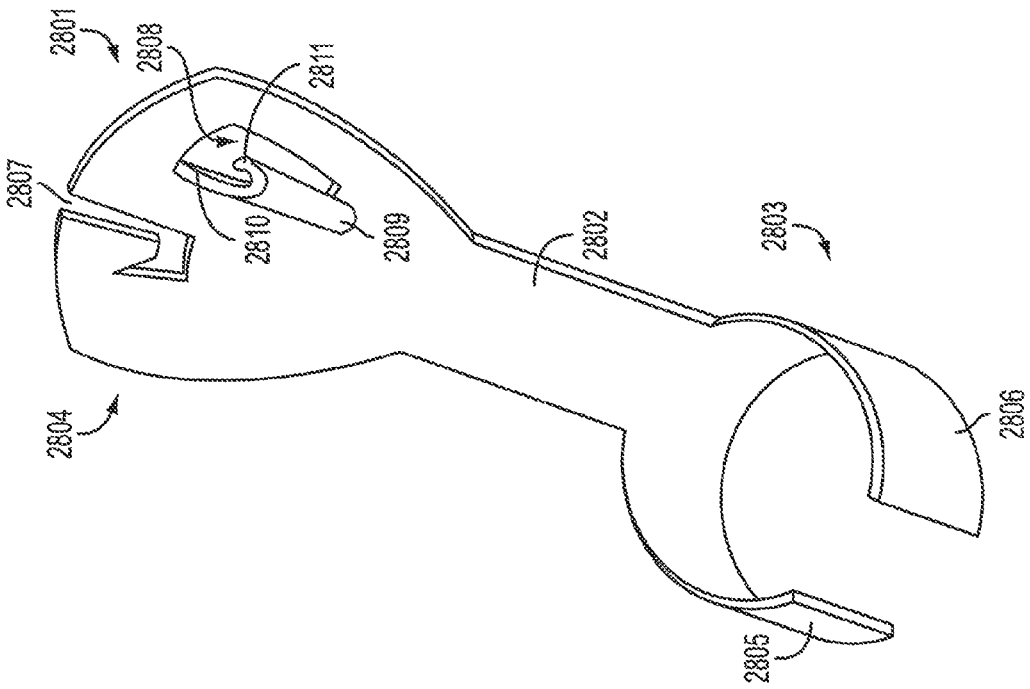
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FIG. 28

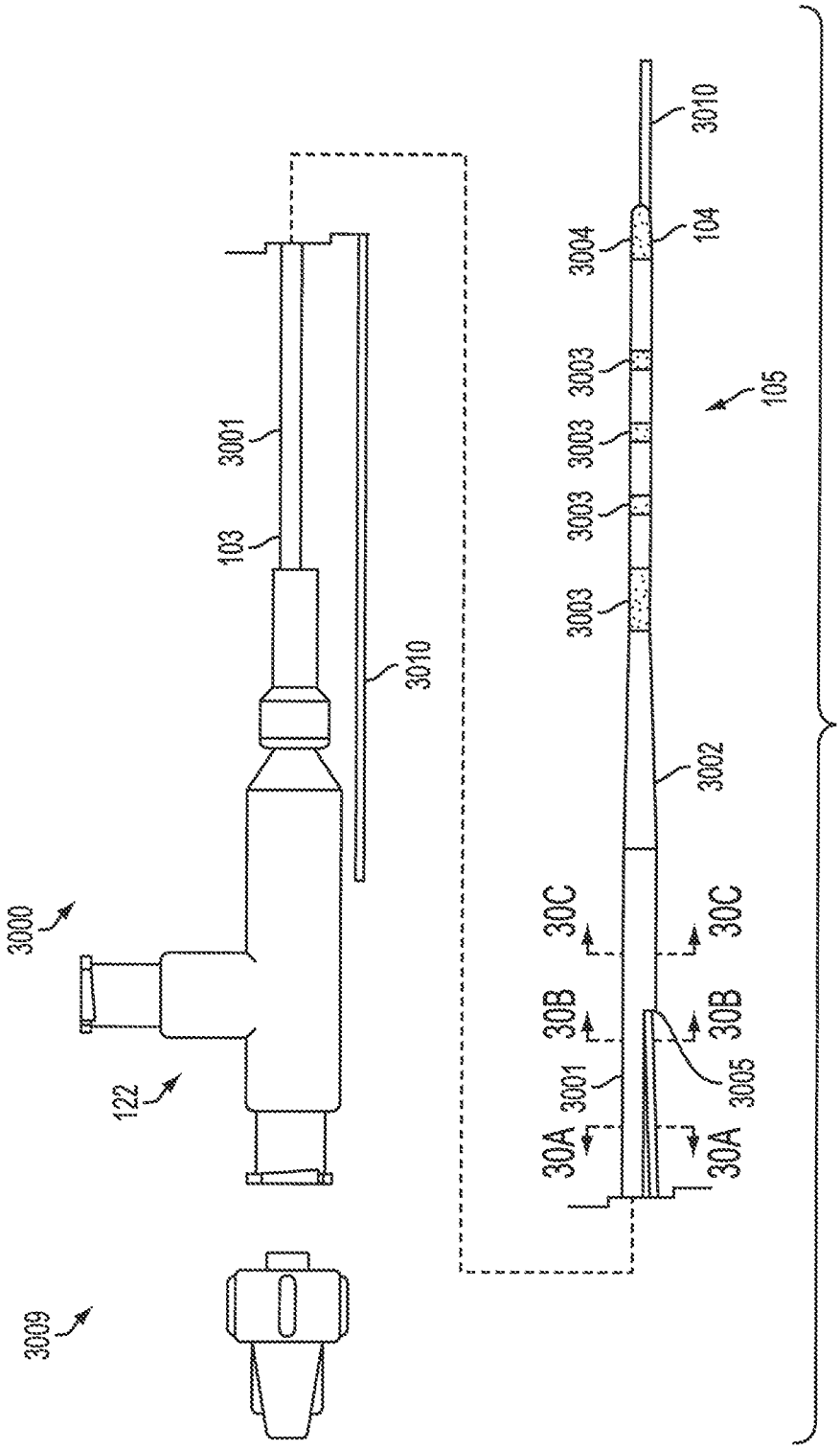
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FIG. 30

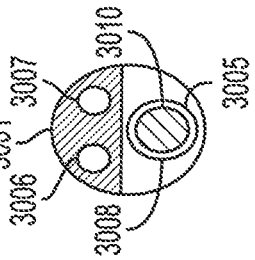

FIG. 30B

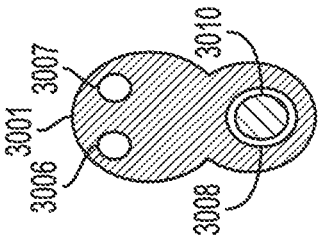

FIG. 30D

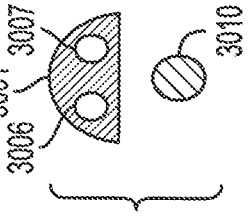

FIG. 30A

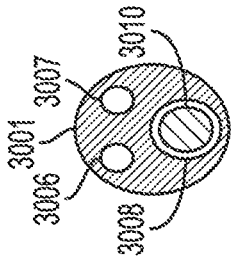

FIG. 30C

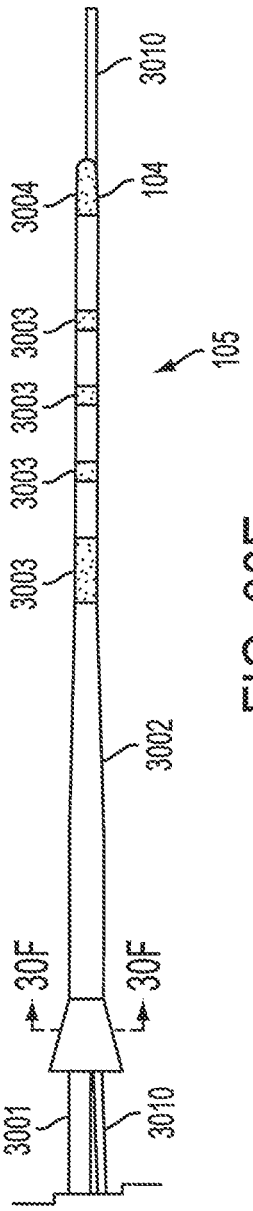

FIG. 30E

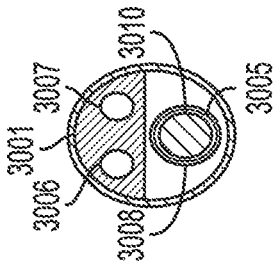

FIG. 30F

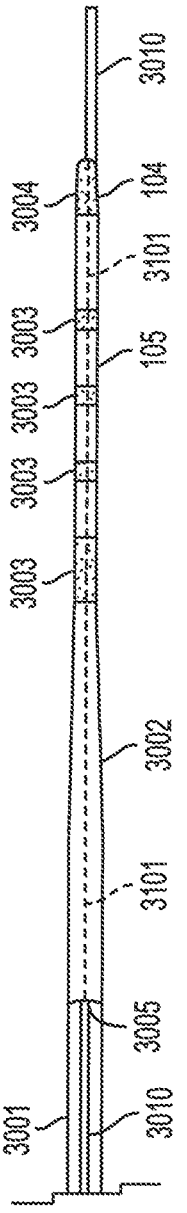
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FIG. 31

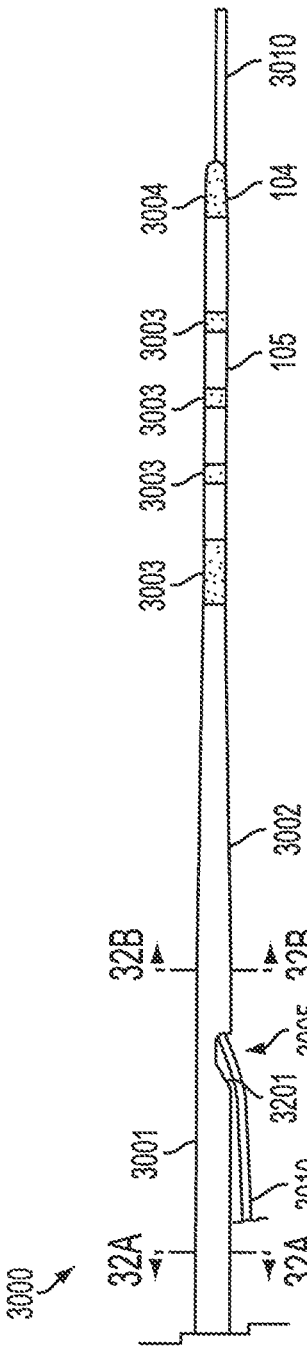

FIG. 32

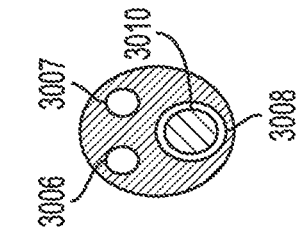

FIG. 32B

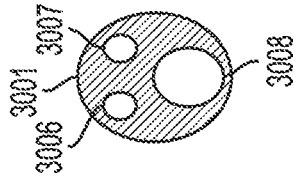

FIG. 32A

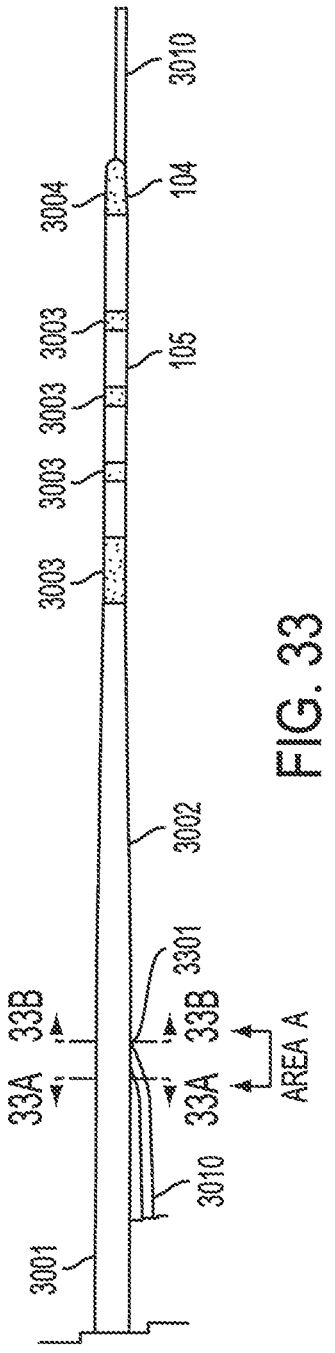

FIG. 33

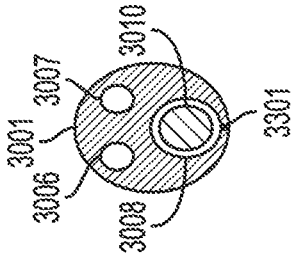

FIG. 33B

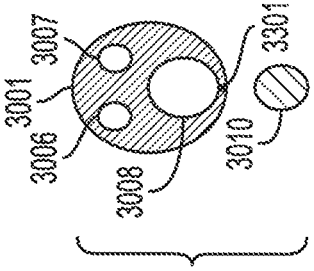

FIG. 33A

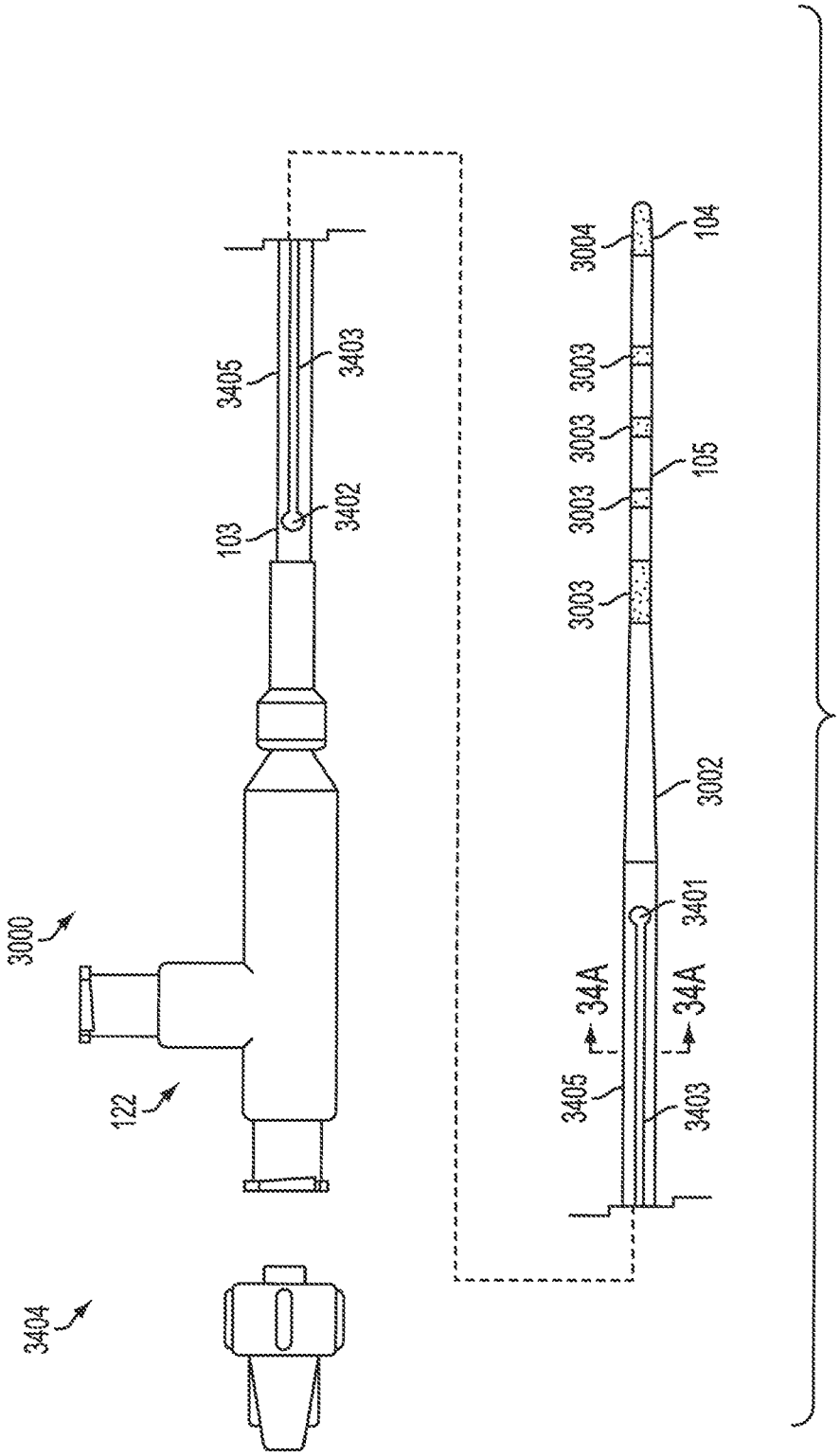
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FIG. 34

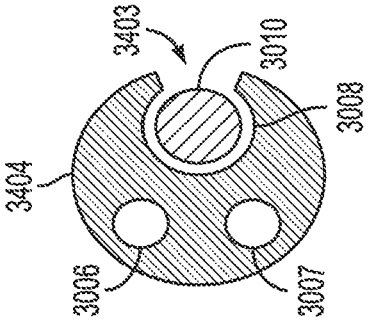

FIG. 35A

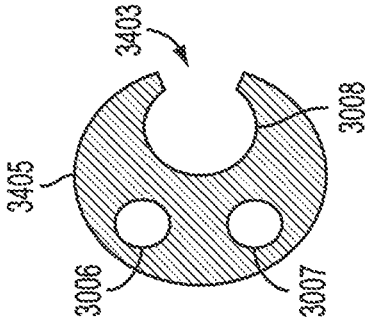

FIG. 34A

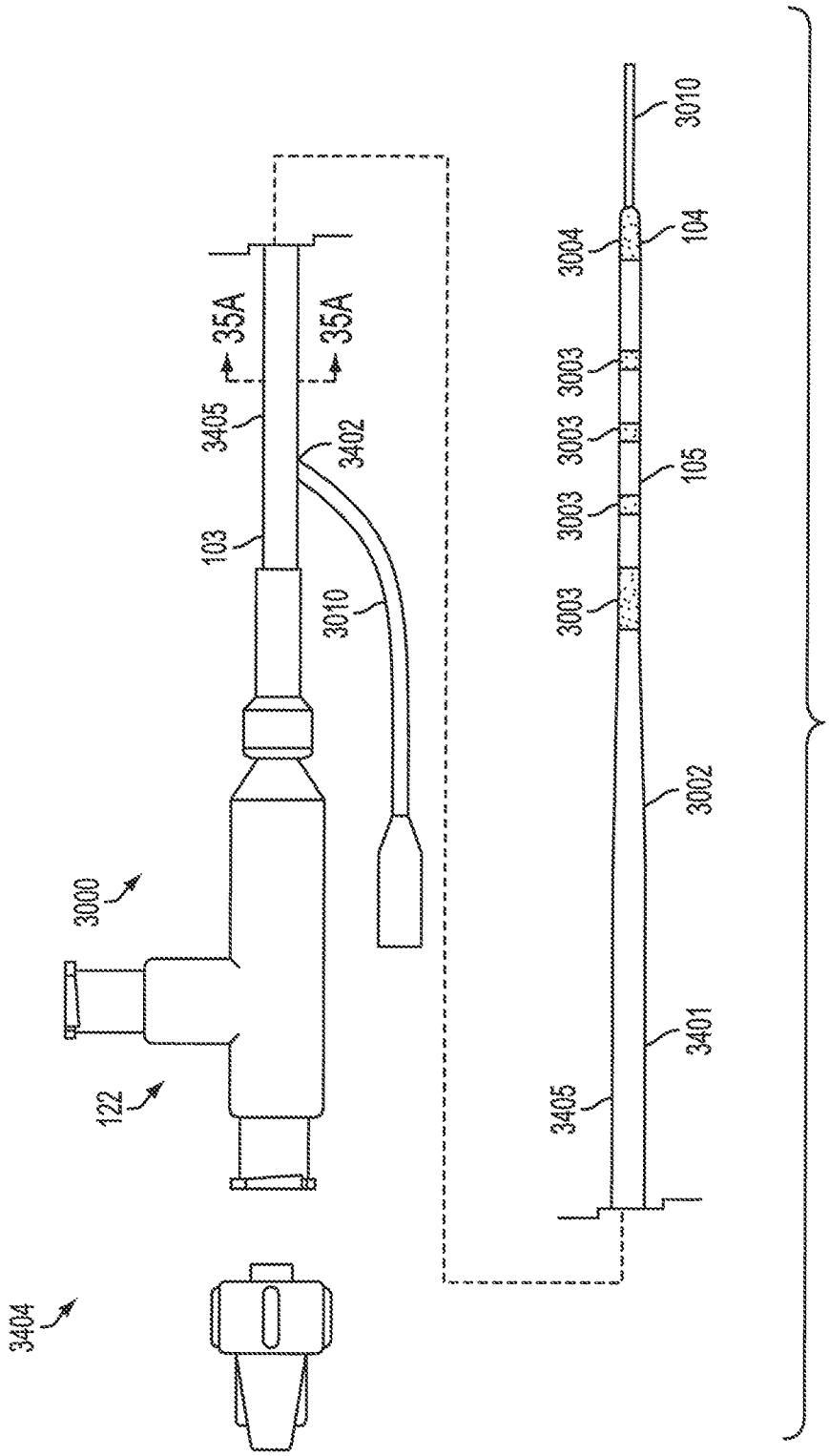
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FIG. 35

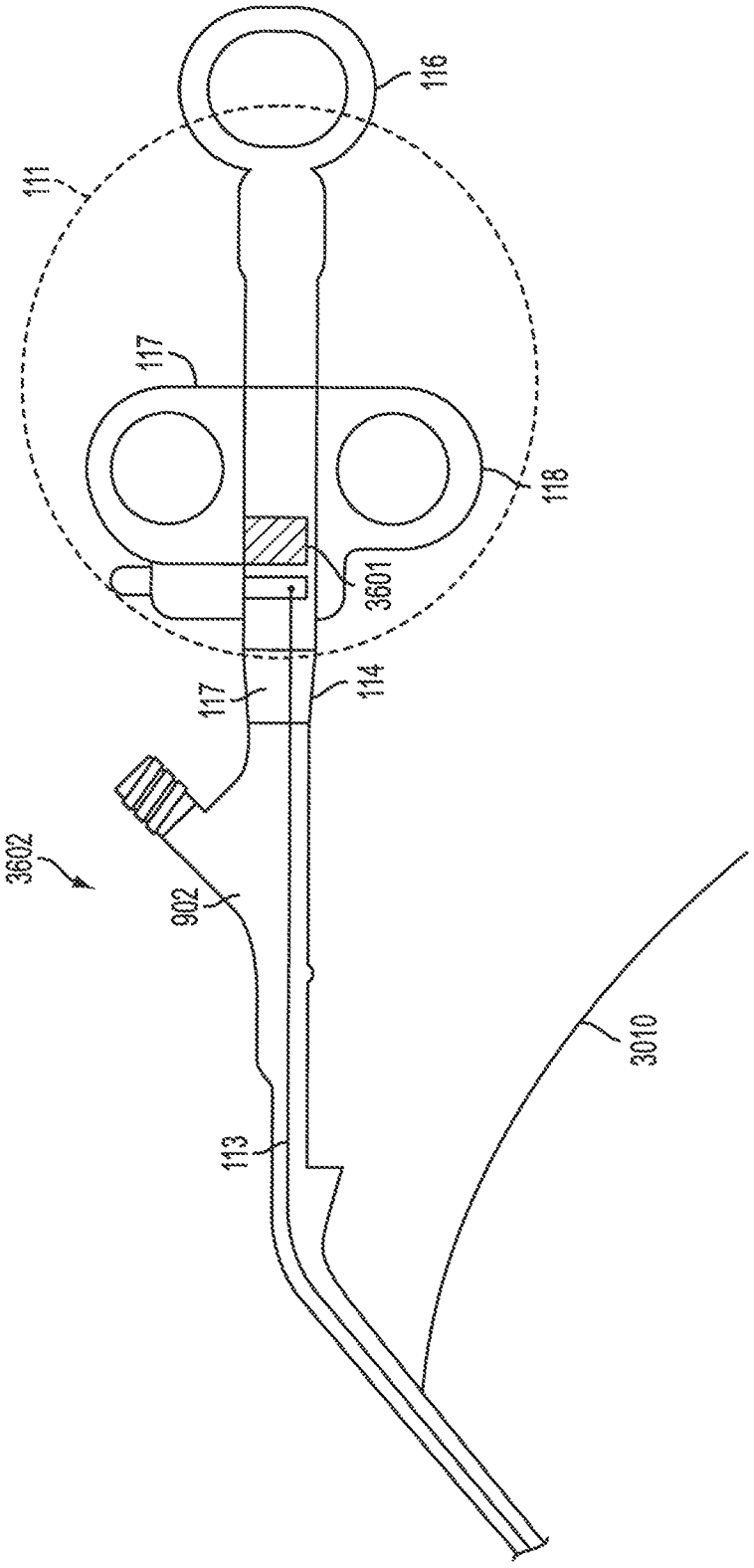

FIG. 36

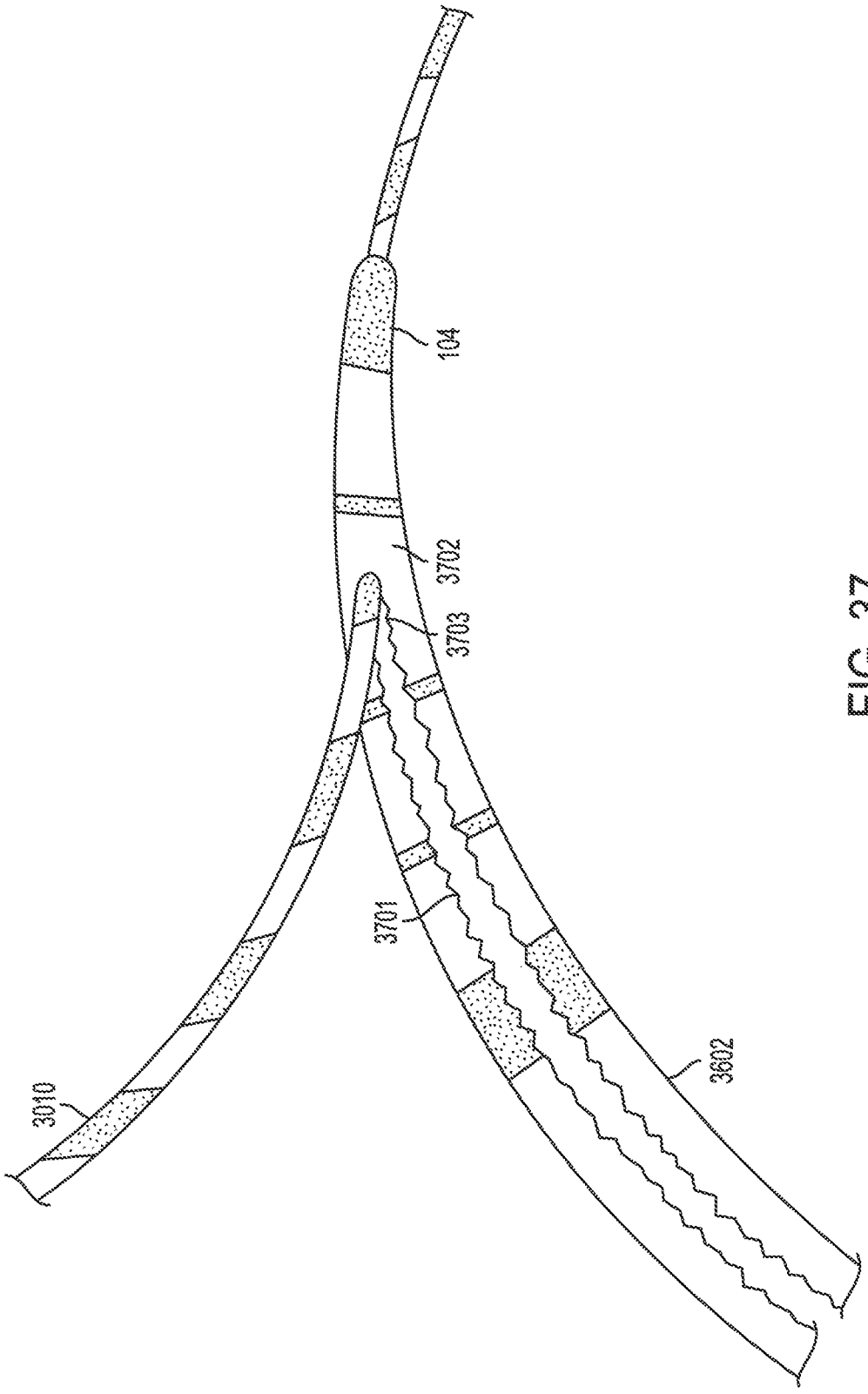

FIG. 37

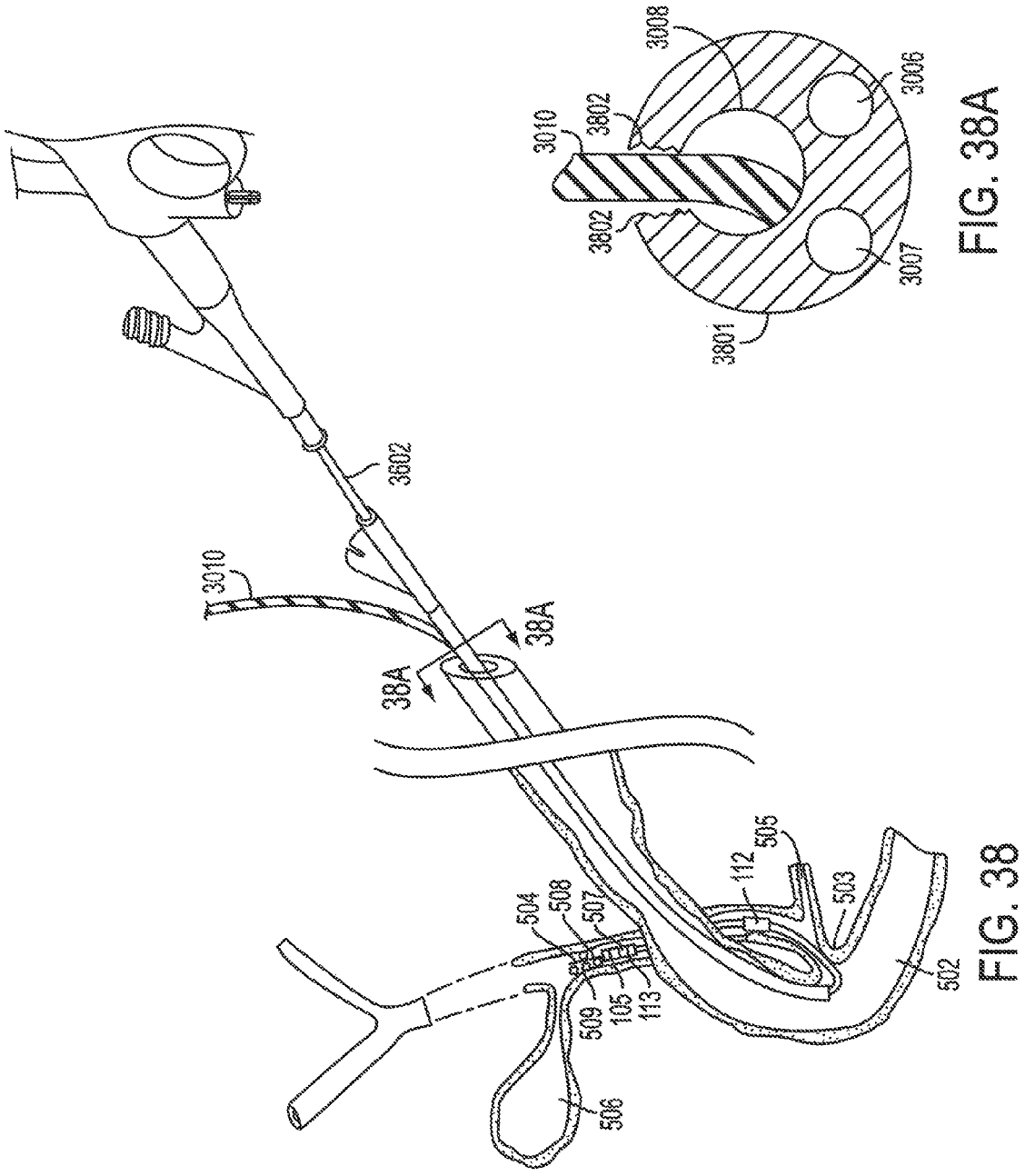

FIG. 38

FIG. 38A

METHOD OF AND APPARATUS FOR POSITIONING AND MAINTAINING THE POSITION OF ENDOSCOPIC INSTRUMENTS

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/561,183, filed Jul. 30, 2012, now U.S. Pat. No. 8,579,895; which is a continuation of U.S. patent Ser. No. 12/639,709, filed Dec. 16, 2009, now U.S. Pat. No. 8,231,621; which is a continuation of U.S. patent application Ser. No. 10/991,477, filed Nov. 19, 2004, now U.S. Pat. No. 7,635,363; which is a continuation of U.S. patent application Ser. No. 10/003,678, filed Dec. 6, 2001, now U.S. Pat. No. 6,827,718; which is a continuation-in-part U.S. patent application Ser. No. 09/928,655, filed Aug. 14, 2001, now U.S. Pat. No. 6,676,659, the entire disclosures of which are all incorporated herein by reference in their entirety.

This application is also related to commonly assigned U.S. Pat. Nos. 5,921,971; 6,007,522; 6,096,009; 5,547,469; 5,683,362; and 5,868,698, the entire disclosures of which are all incorporated herein by reference in their entirety.

BACKGROUND

The present invention relates to apparatus and methods used in positioning and maintaining the position of devices used in catheter procedures within the human anatomy. The present invention includes steerable devices, locking mechanisms and rapid exchange technologies to minimize or eliminate movement of endoscopic instruments during endoscopic procedures.

Historically, the migration of gallstones into an individual's common bile duct was corrected by general surgical procedures. A surgeon would incise the bile duct and remove the gallstones and normally remove the gallbladder. In recent years, less invasive treatment modalities have replaced these general surgical procedures and reduced patient trauma, long hospital stays and recovery periods.

For example, U.S. Pat. No. 4,696,668 and U.S. Pat. No. 4,781,677, both to Wilcox, disclose a treatment modality involving the administration of a dissolution agent in the bile duct to essentially dissolve any gallstones. More specifically, a catheter contains several lumens for inflating and deflating each of two balloons, venting bile, and infusing and aspirating the dissolution agent. Inflating the balloons occludes the bile duct at two spaced sites and creates a sealed spaced that receives the dissolution agent. As the space is sealed from the remaining biliary tree, the dissolution agent finds access to the gallbladder and any gallstones therein through the cystic duct with the exclusion of bile from the gallbladder fundus. The dissolution agent also will be confined in high concentration around bile duct gallstones. After the gallstones dissolve, the balloons are deflated, and the catheter can be withdrawn. In this particular approach, the catheter is directed into the biliary tree using a standard duodenoscope that passes through the alimentary tract. Although this and analogous approaches have the potential of minimizing patient trauma, such treatments require extended placement of the duodenoscope in the patient, exhibit low efficacy and introduce a potential for adverse reactions to the dissolution agents.

In an alternative approach, a surgeon directs a surgical extractor into the biliary tree through at least an incision in the bile duct. For example, in U.S. Pat. No. 3,108,593 to Glassman a surgeon incises both the bile duct and duodenum. Then the surgeon directs an extractor through the bile duct incision, biliary tree, sphincter of Oddi and duodenum to exit through the duodenum incision. This extractor includes a series of longitudinally spaced cages for trapping any gallstones in the bile duct and removing them through either of the incisions.

U.S. Pat. No. 4,627,837 to Gonzalo discloses a catheter device with a pair of inflatable balloons at its distal end. This catheter is led through an incision in the bile duct toward the duodenum. After the distal balloon passes through the sphincter of Oddi, both balloons are expanded to anchor the catheter in place. This enables the catheter to be used for irrigating and flushing through other lumens in order to capture any gallstone in the second balloon for removal through the incised bile duct.

In accordance with still another modality as for the treatment of strictures, a surgeon may insert a catheter device through the bile duct or duodenum for the purpose of dilating or enlarging the sphincter of Oddi. For example, U.S. Pat. No. 4,705,041 to Kim discloses a dilator that is directed through an incision in the bile duct and the sphincter of Oddi. An expandable tip dilates the sphincter of Oddi. U.S. Pat. No. 5,035,696 to Rydell discloses an electrosurgical instrument that is directed through the duodenum and to the sphincter of Oddi for performing a sphincterotomy. This apparatus contains a cutting wire that is heated to cut the sphincter muscle. U.S. Pat. No. 5,024,617 to Karpiel discloses a similar device that can be directed through a duodenoscope. U.S. Pat. No. 5,152,772 to Sewell, Jr. discloses a device for performing a sphincterotomy that is directed through an incision in the bile duct and includes a knife for cutting the sphincter muscle.

The use of the duodenoscope and sphincterotomy devices, such as shown in the Rydell and Karpiel patents, enables an internist to diagnose and treat problems in the biliary tree with less patient invasion than previously possible. For example, modalities as described in these patents eliminate the surgery needed for incising the bile duct. Consequently, these modalities can be performed as outpatient or day surgical procedures. These procedures greatly reduce patient trauma, the length of a hospital stay and recovery times.

The reduced patient trauma, hospital stays and recovery times has resulted in a growth in the number of endoscopic procedures performed for treating abnormal pathologies within the alimentary canal system and biliary tree (including the biliary, hepatic, and pancreatic ducts). The endoscope provides access to the general area of a desired duct using direct visualization. However, the duct itself must be navigated using a catheter in conjunction with fluoroscopy and guide wires,

Catheters are known for treatment of targeted anatomical regions. Known methods and devices for using biliary catheters for accessing the biliary tree for performing catheter procedures are disclosed in Weaver et al., U.S. Pat. No. 5,397,302 and Karpiel, U.S. Pat. No. 5,320,602, the disclosures of which are herein incorporated by reference. In general, for treatment of an abnormal pathology within a patient's biliary tree, an endoscope is first introduced into the mouth of the patient. The endoscope includes a proximal end and a distal end, and has a lumen extending longitudinally between the proximal and distal ends. The endoscope is guided through the patient's alimentary tract or canal until an opening at the distal end of the endoscope is proximate the area to receive treatment. At this point, the endoscope allows other components, such as a catheter, to access the targeted area.

For visualization or treatment within the biliary tree, the distal end of the endoscope is positioned proximate the papilla of Vater leading to the common bile duct and the pancreatic duct. A catheter is guided through the lumen of the endoscope until a distal tip of the catheter emerges from the opening at the distal end of the endoscope.

The catheter may be used for accessing the biliary tree. The distal end of the catheter is guided through the orifice to the papilla of Vater (located near the sphincter of Oddi) leading to the common bile duct and the pancreatic duct. A guide wire may be used in conjunction with the catheter to facilitate accessing a desired location within the biliary tree. The guide wire is inserted in an opening at a proximal end of the catheter and guided through the catheter until it emerges from the distal end of the catheter.

If visualization of the common bile duct is desired, the guide wire is guided into the common bile duct. The catheter is advanced over the guide wire until the distal end of the catheter is positioned in the common bile duct at the desired location. The catheter is now in position for delivery of contrast media for fluoroscopic visualization of anatomical detail within the common bile duct.

Visualization may reveal selected areas within the common bile duct that require treatment. To treat the selected areas, a different catheter is typically required, necessitating a catheter exchange. A catheter exchange typically involves removing the first catheter from the endoscope over the guide wire, and advancing a second catheter over the guide wire to the desired treatment site. Thus, once the guide wire is in place relative to the targeted area, it is highly desirable to maintain the position of the guide wire during subsequent catheter procedures, including during a catheter exchange procedure. If the guide wire moves during such a procedure, the guide wire may have to be re-directed through the body ducts to the target site, which is often a difficult, time consuming and tedious task.

In addition to performing a catheter exchange procedure, it may also be desirable to perform a guide wire exchange procedure. This may be desirable when, for example, a first guide wire is too large to fit through a desired body duct, or otherwise lacks the desired characteristics. Under these circumstances, a physician may leave the catheter in place, withdraw the first guide wire from the catheter, and insert a second guide wire through the catheter to the desired site. During this procedure, the catheter guides the guide wire to the desired site. Thus, once the catheter is positioned at a target site, it is highly desirable to maintain the position of the catheter during a guide wire exchange procedure so that the second guide wire may be guided directly to the desired site in a minimum amount of time.

For example, if an internist determines that gallstones are present in the biliary tree, particularly the common bile duct, the internist can insert a duodenoscope into the duodenum to view the sphincter of Oddi. Then a first catheter can be advanced through the working channel of the duodenoscope with or without a guidewire and directed through the sphincter of Oddi into the biliary tree. Contrast agent injected through the catheter enables fluoroscopy or other imaging procedures to confirm the presence of gallstones within the biliary tree. Next, the internist exchanges the first catheter for a second catheter for performing a sphincterotomy such as the types disclosed in the above-identified Rydell and Karpiel patents. The second catheter is then exchanged for a third catheter such as shown in the Glassman patent or some other equivalent retrieval catheter for drawings gallstones through the enlarged sphincter of Oddi. Thereafter, the retrieval catheter is manipulated to release the gallstone into the duodenum. The catheter, any guidewire and the duodenoscope can then be removed to complete the procedure.

This procedure is significantly less traumatic to the patient than other prior art procedures because the only incision occurs during the sphincterotomy. However, this procedure, as described above, requires three separate catheters and two catheter exchanges. These exchanges are required because the first, second and third catheters function solely to inject contrast agent to perform the sphincterotomy and to dislodge gallstones, respectively. The time required for performing each catheter exchange can increase patient trauma and increase the duration of the procedure and reduce efficiency. Moreover, each such procedure requires the use of two or three separate catheter devices.

Multi-lumen catheters are available which typically reduce the number of catheters and catheter exchanges used during a procedure and thereby reduce both the time required and the patient's trauma while increasing efficiency. A common problem today concerns the accurate placement of an endoscopic instrument such as a cutting device. Secondly, once the cutting device, such as a sphincterotome, Ultratome, Rapid Exchange, Fluorotome, Papillotome or similar device is properly positioned, the position of the device must be maintained during the cutting procedure. An example of a common problem with these devices is that after the device is positioned and left unattended "set relaxation" occurs in which the bow of a cutting instrument undesirably relaxes or straightens out without operator interaction.

Even with multi-lumen catheters, exchanges may be required. To maintain the position of a guide wire and/or catheter during an exchange, a physician typically must grasp the proximal end of the guide wire and/or catheter with one hand, and perform the corresponding exchange with the other. This is difficult, and often results in the movement of the guide wire and/or catheter.

In general, a need exists for an apparatus and method for accurate positioning of endoscopic instruments, such as cutting devices, and the maintenance of the position of the device.

SUMMARY

Therefore, this invention provides an apparatus for, and a method of, accurate positioning of endoscopic instruments. Accurate positioning of the instruments is accomplished through the inclusion of a steering ability within the device. After the endoscopic instrument is properly positioned, the present invention uses rapid exchange technology, soft locks, and mechanical locks to maintain the position of the endoscopic instrument. Rapid exchange technology is used to minimize displacement forces present on the guidewire or catheters. Soft locks and mechanical locks resist movements caused by displacement forces.

The present invention includes an apparatus for use in a treatment modality including an enlargement procedure to be performed within a patient. In this embodiment the apparatus includes a catheter for being directed through internal passageways in the patient, and the catheter has a proximal end and a distal end. A proximal portion is adjacent to the proximal end and a distal portion is adjacent to the distal end. The catheter includes a first and at least a second generally parallel lumen, which extend between the proximal and the distal portions. The present invention includes a cutting wire for performing the enlargement procedure extending through the second lumen for operating at the distal portion in response to manipulations at the proximal end. The cutting wire has a distal end attached to the catheter at the distal end of the second lumen. A portion of the cutting wire is external to the catheter along a length coextensive with a portion of the distal portion of the catheter. The catheter also includes a handle for operating the cutting wire from a point proximal of the catheter. A rotatable coupling attaches the handle to the catheter and allows the handle to rotate relative to the proximal end of

the catheter while engaging and rotating a proximal end of the cutting wire. The rotation of the handle causes the distal portion of the catheter to rotate. The present invention also includes a locking mechanism for locking an orientation of a distal portion of the cutting wire.

This embodiment of the present invention may further include a rotation lock which inhibits further rotation of the handle relative to the proximal end of the catheter and a rotation indicator configured to indicate an amount of rotation of the handle relative to the proximal end of the catheter. The rotation indicator may include a visual indicator of the amount of rotation and the visual indicator may include an index marking and a corresponding scale marking providing an indication of the amount of rotation. The rotation indicator may also include a device providing an audible indication in response to the rotation of the handle relative to the proximal end of the catheter. The locking mechanism of the present invention may include an insert positioned between moving parts of the apparatus to resist movement between the moving parts, or an insert which a guidewire passes through the insert and the insert resists movement of the guidewire. The locking mechanism may include evenly spaced detents in a handle body which interact with one or more pawls located in an active cord insert to resist movement of the active cord insert with respect to the handle body.

In another embodiment of the present invention, the invention includes a method of cutting tissue in a body passage including selecting a catheter having a first lumen configured for receiving a wire guide and a second lumen configured for receiving an electrosurgical cutting wire. The catheter is positioned in the passage at a desired position using an endoscope, and the electrosurgical cutting wire is actuated in the second lumen. In this embodiment, the invention includes orientating the electrosurgical cutting wire by rotating a handle relative to a proximal end of the catheter and fixing an orientation of the electrosurgical cutting wire. The orientation of the electrosurgical cutting wire may be fixed by an insert which creates friction between moving parts in the catheter which resists movement between the moving parts. The orientation may also be fixed with detents which interact with pawls to resist movement between an active cord insert and a handle.

Another embodiment of the present invention includes a catheter handle comprising a rotatable coupling configured to allow free rotation of a proximal end of a catheter and a clamping member configured to engage a proximal end of a device extending through a lumen formed in the catheter, whereby rotation of the handle causes rotation of a proximal end of the device in the lumen and a locking mechanism configured to resist movement in a distal end of the device. In this embodiment, the device may include a cutting wire extending from the proximal end of the catheter to and connecting to a distal end of the catheter. A rotation lock may also be included which is engageable to inhibit a rotation of the handle with respect to the proximal end of the catheter.

Another embodiment of the present invention includes a catheter including a shaft having a proximal end and a distal end. The catheter includes a guidewire lumen carried by the shaft extending from a location proximal the distal end of the shaft to a location proximate the distal end of the shaft. Also included is a cutting device extending from the proximal end of the catheter to a distal portion of the catheter and where a distal portion of the cutting device is exterior to the catheter. In this embodiment, means for accessing the guidewire lumen from a location exterior to the catheter shaft, located distal the proximal end of the shaft, are included. These means include a first opening through the wall of the catheter shaft into the guidewire lumen located proximal the distal end of the shaft and a second opening through the wall of the shaft located proximal the first opening. Also included is a channel which gives access to the guide wire lumen extending longitudinally between the first opening and the second opening. Additionally, means for locking an orientation of the cutting device are also included. In this embodiment, the guidewire lumen may be formed integral to the shaft. Additionally, the channel may include an opening extending longitudinally between the first opening and the second opening in communication with the guidewire lumen. The locking means may include an insert positioned between moving parts used to actuate the cutting device wherein the insert resists movement between the moving parts. The locking means may also include detents located in a handle of the catheter and at least one pawl located on an active cord insert where the active cord insert moves with respect to the handle and the detents cooperate with the pawl to resist movement of the active cord insert.

Another embodiment of the present invention includes a method of positioning a cutting device including a shaft having a proximal end and a distal end, within a patient's lumen comprising the steps of: providing a guidewire lumen within the catheter, extending from a location proximal the distal end of the shaft to a location proximate the distal end of the shaft and providing a port through a sidewall of the shaft into the guidewire lumen, the port located distal of the proximal end of the shaft. In this embodiment, a guidewire is moved through the port relative to the shaft, and the catheter is advanced over the guidewire. The cutting device is actuated so as to expose a distal portion of the cutting device exterior of the catheter, and the orientation of the cutting device is fixed.

BRIEF DESCRIPTION OF THE DRAWINGS

The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

FIG. **1** is a plan view of one embodiment of apparatus constructed in accordance with this invention;

FIG. **2** is a cross-section taken along lines **2-2** in FIG. **1**;

FIG. **3** is a cross-section taken along lines **3-3** in FIG. **2**;

FIG. **4** is a cross-section taken along lines **4-4** in FIG. **2**;

FIG. **5** depicts the apparatus of FIG. **1** positioned through a duodenoscope for injecting contrast agent into the biliary tree;

FIG. **6** is an enlarged view that depicts the orientation of the apparatus in FIG. **1** for performing a sphincterotomy;

FIG. **7** depicts the apparatus of FIG. **1** positioned through a duodenoscope for dislodging material within the common bile duct;

FIG. **8** is a plan view of one embodiment of apparatus constructed in accordance with the present invention with a rotatable handle attached to a cutting wire;

FIG. **8**A is a plan view of a snap in handle connection for the apparatus of FIG. **8**;

FIG. **9** is a view of the rotatable handle of the present invention including a rotation lock;

FIG. **10** is a detailed view of the rotation lock of FIG. **9**;

FIG. **11** is a sectional view along line **11-11** of FIG. **10**;

FIG. **12** shows an alignment between the rotatable handle and the bifurcation connector showing zero rotation of the rotatable handle;

FIGS. **13**A-D show alternative embodiments of the rotation lock of the present invention;

FIGS. **14**A-D show cross-sectional areas of the alternate embodiment of FIGS. **13**A-D;

FIGS. **15**A-C show three alternative embodiments of rotation markings for the present invention;

FIGS. **16**A and B illustrate a bowing lock included in the present invention;

FIG. **17** shows a handle of a Rapid Exchange Tome including an insert to resist movement;

FIG. **18** shows an Ultratome "D" connector incorporating an insert to resist movement;

FIGS. **19**A and B show two embodiments of inserts included in a Tome handle to prevent movement;

FIG. **20** shows an insert included in a body or handle to prevent movement;

FIG. **21** shows an Ultratome XL handle including detents to prevent movement;

FIG. **22** shows an active cord insert which includes a pawl which cooperates with the handle of FIG. **21** to prevent movement;

FIG. **23** shows the interaction of the detents of FIG. **21** and pawl of FIG. **22** to prevent movement;

FIG. **24** is a perspective view of an illustrative locking device;

FIG. **25** is a partial side view of an illustrative locking device positioned on an endoscope having an angled side port;

FIG. **26** is a partial side view detailing the illustrative locking device of FIG. **25**;

FIG. **27** is a perspective view of another illustrative locking device;

FIG. **28** is a perspective view of yet another illustrative locking device;

FIG. **29** is a partial side view of another illustrative locking device positioned on an endoscope having an angled side port;

FIG. **30** is a partial elevational view of a catheter in accordance with the present invention having a guidewire lumen for facilitating rapid catheter exchange with a guidewire passing therethrough;

FIG. **30**A is a cross-sectional view of the catheter of FIG. **30** taken along line **30**A-**30**A;

FIG. **30**B is a cross-sectional view of the catheter of FIG. **30** taken along line **30**B-**30**B;

FIG. **30**C is a cross-sectional view of the catheter of FIG. **30** taken along line **30**C-**30**C;

FIG. **30**D is a cross-sectional view of an alternative embodiment of the catheter of FIG. **30** in accordance with the present invention, also taken along line **30**C-**30**C;

FIG. **30**E is a partial elevational view of an alternative embodiment of the catheter in accordance with the present invention;

FIG. **30**F is a cross-sectional view of the catheter of FIG. **30**E taken along line **30**E-**30**F;

FIG. **31** is a partial elevational view of another embodiment of the catheter in accordance with the present invention;

FIG. **32** is a partial elevational view of another embodiment of the catheter in accordance with the present invention;

FIG. **32**A is a cross-sectional view of the catheter of FIG. **32** taken along line **32**A-**32**A;

FIG. **32**B is a cross-sectional view of the catheter of FIG. **32** taken along line **32**B-**32**B;

FIG. **33** is a partial elevational view of another embodiment of the catheter in accordance with the present invention;

FIG. **33**A is a cross-sectional view of the catheter of FIG. **33** taken along line **33**A-**33**A;

FIG. **33**B is a cross-sectional view of the catheter of FIG. **33** taken along line **33**B-**33**B;

FIG. **34** is a partial elevational view of another embodiment of the catheter in accordance with the present invention;

FIG. **34**A is a cross-sectional view of the catheter of FIG. **34** taken along line **34**A-**34**A;

FIG. **35** is a different partial elevational view of the catheter of FIG. **34** having a guidewire disposed therein;

FIG. **35**A is a cross-sectional view of the catheter of FIG. **35** taken along line **35**A-**35**A showing the guidewire received within the lumen of FIG. **34**;

FIG. **36** shows a cut away diagram of an embodiment of the current invention which incorporates the rotating handle, locking mechanism and rapid exchange technology into a single catheter;

FIG. **37** shows a non-directional tear in a thinned-wall catheter;

FIG. **38** shows the thinned wall catheter of FIG. **37** positioned through an endoscope detailing the relationship of the guidewire and the catheter when a rapid exchange catheter is used; and

FIG. **38**A is a sectional view along line **38**A-**38**A of FIG. **38**.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

FIG. **1** depicts catheter apparatus **100** that has the capability of injecting a contrast agent into the biliary tree, accurately positioning and maintaining the position of a cutting wire, of performing a sphincterotomy and of dislodging a gallstone into the duodenum. Apparatus **100** includes a catheter **101** which, for purposes of definition, includes proximal portion **102** extending from proximal end **103** and distal end **104** with distal portion **105** extending a short distance proximally from distal end **104**. In a typical application, catheter **101** will have a working length of 200 cm and distal portion **105** will have a length of 6 cm to 9 cm. Normally, distal portion **105** will have a diameter that is smaller than the diameter of proximal portion **102** to increase the flexibility of distal portion **105**. The reduction in diameter also makes distal end **104** less traumatic and allows distal portion **105** to reach smaller passages while allowing the larger proximal portion **102** to provide necessary hoop strength and rigidity, particularly where proximal portion **102** is coextensive with the working channel of a duodenoscope. For example, the proximal and distal portions might have diameters corresponding to 7 Fr and 5.5 Fr catheter sizes (i.e., 0.09" and 0.07", respectively).

As shown particularly in FIG. **2**, catheter **101** has three lumens. First lumen **201** has a diameter that is greater than either second lumen **202** or third lumen **203**. In one particular embodiment, first lumen **201** has a diameter of 0.040" in proximal portion **102** that reduces to about 0.037" in distal portion **105** to receive a standard 0.035" guidewire. In addition, first lumen **201** is offset from the center of catheter **101**. While FIG. **2** shows lumens of various diameters, the present invention may be implemented in a catheter which includes lumens of identical size.

The cross section of both second lumen **202** and third lumen **203** are shown smaller than the cross section of first lumen **201** and are radially offset from the centerline of catheter **101**, from each other and from first lumen **201**. In one particular embodiment, the cross section of third lumen **203** has a diameter of 0.028" in proximal portion **102** that reduces to about 0.020" in distal portion **105**, and second lumen **202** has an internal diameter of 0.028" in proximal portion **102** that reduces to about 0.020" in distal portion **105**. As described later, this third lumen **203** carries a cutting wire for performing a sphincterotomy and for allowing the infusion of

a contrast agent at reasonable rates. The orientation of the cutting wire can also be positioned as desired as further described herein. The angular spacing between second lumen **202** and third lumen **203** is about 45 degrees, and the angular spacing between first lumen **201** and each of lumens **202** and **203** each is about 157.5 degrees. In this configuration and with these dimensions, proximal portion **102** readily passes through the working channel of any duodenoscope.

Referring again to FIGS. **1** and **2**, each of lumens **201**, **202** and **203** includes an entry port in proximal portion **102** and an exit port in distal portion **105**. Generally, and as described in more detail later, first lumen **201** has an exit port through distal end **104**, while the exit ports for lumens **202** and **203** can be sited at different locations in distal portion **105** depending upon a particular application.

In FIG. **1**, the entry ports in proximal portion **102** adjacent proximal end **103** include an entry port **106** that provides access to first lumen **201** and includes an optional Luer lock fitting **107**. Proximally positioned entry port **108** provides access to second lumen **202** and includes optional Luer lock fitting **109**. Proximal entry port **110** for third lumen **203** is located coextensively with a portion of handle **111** attached to proximal end **103**. One of ordinary skill in the art would understand that this specific configuration is given as an example and not meant to limit the invention. Various other configurations would be apparent to one of ordinary skill in the art to practice the invention described herein.

Referring to FIG. **3**, the distal portion **105** of catheter **101** in this particular embodiment carries expansible balloon **112** proximally of the excursion of cutting wire **113** (FIG. **1**) externally of catheter **101**. Second lumen **202** emerges at distal exit port **301** through the side of catheter **101** with the interior of expansible balloon **112**. An extension **302** of second lumen **202** beyond distal port **301** is sealed by known methods of manufacture. Consequently, fluid forced through entrance port **108**, as by a syringe (not shown) attached to Luer lock fitting **109**, expands balloon **112** into an occluding orientation with an inflated diameter in the range up to 20 mm.

First lumen **201** extends through catheter **101** and terminates with exit port **303** in distal end **104**. Thus first lumen **201** is adapted for receiving a guidewire through the entry port **106** that will extend through catheter **101** and exit via exit port **303** in distal end **104** and allow the catheter to slide over that guidewire.

Referring to FIG. **4**, distal end **401** of cutting wire **113** attaches to a clamp **402** formed at the distal end of third lumen **203**. Spaced skived ports **403** and **404** allow active portion **405** of the cutting wire **113** to emerge from catheter **101** through skived aperture **403**, parallel catheter **101** exteriorly thereof, and return into third lumen **203** through port **404** and reinforcing sleeve **406**. Cutting wire **113** then extends through third lumen **203** to handle **111** shown in FIG. **1** where it emerges as proximal end portion **114**.

Handle **111**, as shown in FIG. **1**, includes central member **115** terminating with thumb ring **116**. Central member **115** extends through and slides with respect to body section **117** having opposed finger rings **118**. Central member **115** also attaches to catheter **101** at catheter hub assembly **122** and is therefore an extension of catheter **101**. Body section **117** additionally includes internal connector **119** for clamping proximal end **114** of cutting wire **113**. Thus, when body section **117** is at its distal position as shown in FIG. **1**, distal portion **105** of catheter **101** is in essentially a straight line as shown in FIG. **1** and FIG. **4** with active portion **305** of cutting wire **113** being closely adjacent catheter **101**. Retracting body section **117** causes cutting wire **113** to bend distal end **104** upwardly as shown in FIG. **6** to a position that is essentially at right angles to the main axis of the catheter, as will be shown later.

Internal connector **119** and cutting wire **113** are generally conductive members that attach through RF connector **120** to RF heating source **121**. The use of such RF heating sources **121** for energizing cutting wire **113** thereby to cut the sphincter muscle is well known in the art and represents one possible sphincterotomy procedure that can be adapted for the apparatus of this invention and is not described further. RF connector **120** is also known as an active cord attachment, and the cord from the RF heating source may be referred to as an active cord.

With this description of the apparatus structure, it will now be possible to understand its use in a particular application. FIG. **5** discloses, in a partially broken and schematic view, the positioning of duodenoscope **501** in duodenum **502** adjacent sphincter of Oddi **503**. Catheter **101** such as constructed in FIG. **1** passes through sphincter of Oddi **503** into the common bile duct **504**, bypassing pancreatic duct **505**. Distal end **104** does not extend to gallbladder **506**.

Fluoroscopy allows the appropriate positioning by utilizing a series of radio-opaque markers **507** at distal portion **105** that may include clamp **402** and reinforcing sleeve **406** in FIG. **4**. Catheter **101** can be positioned with or without the presence of guidewire **508** in first lumen **201** shown in FIGS. **5**, and **7**. For purposes of injecting the contrast agent, any guidewire **508** can be withdrawn to allow the contrast agent to be injected through first lumen **201** for purposes of fluoroscopic examination to confirm the presence of one or more gallstones **509**. It is also possible during the operation to expand balloon **112** to occlude common bile duct **504** and block any migration of contrast agent into duodenum **502** or pancreatic duct **505**.

FIG. **6** is an enlarged view showing duodenum **502**, sphincter of Oddi **503**, portions of pancreatic duct **505** and common bile duct **504**. In FIG. **6**, catheter **101** has been positioned relative to the duodenoscope **501** through the opening of sphincter of Oddi **503**. Body section **117** of handle **111** in FIG. **1** has been drawn proximally to deflect distal portion **105** into essentially a right angle configuration such that cutting wire **113** abuts a portion of sphincter of Oddi **503**. The application of RF heating to cutting wire **113** then will cut sphincter of Oddi **503** and enlarge the opening therethrough. As will be apparent, the sphincterotomy is performed with direct visualization of the sphincter of Oddi **503** through duodenoscope **501**.

Moreover, as has been observed by others, catheters having guidewire and cutting wire lumens tend to assume a particular angular orientation when distal portion **105** emerges from the duodenoscope. This orientation is essentially independent of the angular position of the catheter when it is inserted into duodenoscope **501**. The offset nature of lumen **203** as shown in FIG. **2**, improves the location of cutting wire **113** as distal portion **105** passes through sphincter of Oddi **503**. Specifically, the angularly offset brings cutting wire **113** into better alignment with common bile duct **504** and displaces the cutting wire from pancreatic duct **505**.

FIG. **7** depicts the catheter after the sphincterotomy and after catheter **101** is advanced over guidewire **508**, if used. FIG. **7** also discloses catheter **101** after balloon **112** has been moved beyond gallstone **509** in bile duct **504**. Balloon **112** is expanded so that upon withdrawal of catheter **101** balloon **112** will dislodge gallstones **509** and sweep them through sphincter of Oddi **503** into duodenum **502**.

One of ordinary skill in the art would appreciate that the present invention would include switching the orientation of

balloon **112** and cutting wire **113**. In other words, FIGS. **1**, **3** and **4** illustrate an embodiment in which balloon **112** is located proximally of cutting wire **113**. In an alternative embodiment of the present invention, the balloon may be located distally of the cutting wire. One of ordinary skill in the art would also appreciate that the location of the exit ports for the various lumens may be sited at different locations in distal portion **105** depending upon the particular application. For example, second lumen **202** may have an exit port located in distal end **104** of distal portion **105**. This configuration may be desirable for injecting contrast agent directly into the biliary tree while the guidewire remains in place in first lumen **201**.

As one of ordinary skill in the art would appreciate, proper positioning of the endoscopic instrument, such as cutting wire **113**, is crucial in the proper treatment of obstructive disease. As explained above, catheters having guidewire and cutting wire lumens tend to assume a particular angular orientation when distal portion **105** emerges from duodenoscope **501**. Since this orientation is essentially independent of the angular position of the catheter when it is inserted into duodenoscope **501**, a need exists to properly position cutting wire **113**. Safe and effective results are only obtained through precise positioning of cutting wire **113** and control or maintenance of the portion of the exposed cutting wire.

Due to inconsistencies in the sphincterotome, anatomy, and endoscope manipulation, it is difficult to accurately and consistently position the sphincterotome for proper cannulation. The steerable sphincterotome of the present invention allows the physician to control the position of distal end **104** of the device independently of the endoscope and adjust for inconsistencies in the device and the anatomy. According to the present invention, handle **111** to which cutting wire **113** is attached is freely rotatable relative to catheter **101**. Rotating handle **111** of the present invention induces a twisting of attached cutting wire **113**, which allows orientation of distal end **104** without rotating proximal end **103** of attached catheter **101**.

FIG. **8** shows handle **111** secured to cutting wire **113** at **801** but rotatable relative to the catheter hub assembly **122** at **802**. This configuration provides a mechanism to rotate cutting wire **113**, thereby transmitting a force used to rotate device end **104**. With handle **111** rotating independently of catheter hub assembly **122** at proximal end **103**, the force can be applied directly to distal end **104** without twisting the entire shaft. A rotation lock may be included to maintain the orientation of the tip and a rotation marking may be included to indicate the amount of rotation present. An integrated molded luer port assembly **803** for two and three lumen catheters may be provided to snap into rotatable handle **111** to facilitate fast and economical manufacturing, as shown in FIGS. **8** and **8**A.

FIG. **9** shows a rotation lock of the present invention. Rotation lock **901** enables the user to maintain the orientation of distal end **104**. One method of maintaining the orientation of distal end **104** is to maintain the position of handle **111** relative to bifurcation connector **902** after handle **111** has been rotated. Rotation lock **901** allows the user to release handle **111** at any time during the procedure, while maintaining the orientation of handle **111** and preventing further rotation while rotation lock **901** is engaged. Maintaining the position of handle **111** maintains the orientation of distal end **104** in the desired orientation. Maintaining the orientation of the distal end **104** reduces the amount of time and effort required to cannulate if distal end **104** moved. Preventing undesired movement of distal end **104** may also prevent patient injury. With respect to rotation of handle **111**, one of ordinary skill in the art would appreciate that body section **117** rotates with handle **111**, and handle **111** is used as a shorthand when discussing rotation.

FIG. **10** shows two pair of mating detents **1001** and slots **1002** which may be used to create rotation lock **901**. Detents **1001** and slots **1002** are located along the central axis of body section **117** at the intersection of body section **117** and bifurcation connector **902**. In FIG. **10**, the two pair of detents **1001** and slots **1002** are located 180° apart relative to the central axis. This configuration creates a lock position every half rotation of handle **111**. During use of the device, as handle **111** is rotated, detents **1001** become disengaged from slots **1002**. As detents **1001** become disengaged, they compress slightly. As handle **111** reaches a position 180° from where rotation began, detents **1001** recover from their compressed state, and engage with slots **1002** once again. As detents **1001** traverse from one position to the next, there is a noticeable amount of friction between the mating components. This friction is great enough that handle **111** can be released at any time without fear of losing the orientation position of distal end **104**.

Rotation lock **901** also serves a secondary function of keeping distal end **104** locked in the home position while catheter **101** is being removed from the package, inserted into the endoscope, and manipulated through the endoscope. Without this feature, the initial orientation position of distal end **104** would become unpredictable. FIG. **11** shows a detailed diagram of the interaction between detents **1001** and slots **1002**.

Referring to FIG. **12**, when detents **1001** and slots **1002** are engaged, bifurcation connector **902** and finger rings **118** all lie in the same plane. This acts as a rotation marker. When finger rings **118** are rotated into the same plane as bifurcation connector **902**, the rotation lock is engaged, thus signaling 180° of rotation from the last position. The use of a marker such as this allows the user to more easily keep track of how much handle **111** has been rotated. This is helpful if the user desires to move distal end **104** back to its original position. In effect, the user will know, for example, that handle **111** has been rotated three clicks from the original position. Therefore, to return handle **111** to the original position, it must be rotated three clicks in the opposite direction.

FIGS. **13**A-**13**D show alternative embodiments of rotation lock **901**. FIG. **13** A shows a pure frictional lock. The connection of bifurcation connector **902** to handle **111** could be designed such that rotation lock **901** is purely a function of frictional interference between the two components. Alternative embodiments could include different types of assembly joints to create this friction. In the primary embodiment, the assembly of the two components is accomplished by mating a post or protrusion of the bifurcation connector to a hole of the same size and shape. Alternative embodiments could reverse this, so that a post or protrusion is part of the main body of handle **111**. The friction lock could also be built into the mating faces of main body and bifurcation connector, which are perpendicular to the major axis. FIG. **14**A shows a cross section of rotation lock **902** along **14**A-**14**A of FIG. **13**A.

FIG. **13**B shows an oval post lock embodiment of the present invention. The connection of bifurcation connector **902** to handle **111** could also be designed incorporating an ovalized post **1301** and hole **1302**. In this embodiment, as handle **111** is rotated relative to bifurcation connector **902**, ovalized hole **1302** would deform, allowing oval post **1301** to rotate. As handle **111** reached a rotation of 180", ovalized hole **1302** would conform back to its original shape, thus locking handle **111** in place. As shown in FIGS. **13**C and **13**D, this basic concept may be expanded to incorporate other shapes

rather than oval as shown in FIG. **13**B. One of ordinary skill in the art would appreciate that the shape of the geometry, however, governs the degrees of rotation between locked positions. For example, if post **1301** and ovalized hole **1302** configuration were made up of mating equilateral triangles (FIG. **13**C), there would be 120° of rotation between locked positions. Using a square configuration (FIG. **13**D), would give 90° between locked positions. FIG. **14**B illustrates the cross-sectional area across **14**B-**14**B of FIG. **13**B. FIG. **14**C illustrates the cross-sectional area of FIG. **13**C across **14**C-**14**C, and FIG. **14**D illustrates the cross-sectional area of FIG. **13**D along cross-section **14**D-**14**D.

FIGS. **15**A-C show alternative embodiments by which a rotation marker **1501** may be created and included in the present invention. One of ordinary skill in the art would understand these embodiments may be expanded. To aid the user in knowing exactly how much handle **111** has been rotated from its original and/or last position, several forms of visual markers can be incorporated into the design. One alternative embodiment is comprised of a set of lines placed radially, around the major axis, at the area where body section **117** and bifurcation connector **902** meets (FIG. **15**A). A single line on the stationary component, bifurcation connector **902**, would match up with a corresponding line on body section **117**. As handle **111** is rotated relative to bifurcation connector **902**, the series of lines or arrows on body section **117** would rotate past the stationary line on bifurcation **902**. Each line would indicate an incremental amount of movement. For example, if there were four, equally spaced lines on the body, each line that passed the marker on the bifurcation connection would signify 90° of rotation.

This feature could be further enhanced by many methods. A series of numbers rather than lines could be used to signify the amount of rotation (FIG. **15**C). Alternating colors could also be used to signify the amount of rotation. Alternating line patterns could be used as well (FIG. **15**B).

Another alternative embodiment may use audible tones such as clicks to make the user aware of the amount of rotation. One method of incorporating this feature may be to design the rotation lock features so that a click is clearly audible at predetermined points along the rotational travel of the body. One of ordinary skill in the art would also appreciate that there are several alternative means by which a connector can be created and that each of these alternatives is included in the present invention. One of ordinary skill in the art would also appreciate that the connector design of the present invention could easily be modified to accommodate three or more lumens.

FIGS. **16**A and B show additional embodiments of the present invention which may include handle **111** similar to that previously described, but with the addition of a bowing lock. A bowing lock would aid the user in that handle **111** could be released at any time and at any orientation, and distal end **104** would maintain its bowed position. Just as rotation lock **901** provides for a safer and more efficient procedure, the bowing lock would perform similarly. The bowing lock could be incorporated into the design in many ways. The bowing lock, in its simplest form, would consist of friction lock **1601** created between finger rings **118** and body section **117** (FIG. **16**A). An alternative to this design would create a similar friction lock, but would use the surfaces between wire termination **1602** and body section **117** (FIG. **16**B). The friction lock shown in FIG. **16**B is enhanced by incorporating several lock ribs **1603**. Lock ribs **1603** would be used to hold distal end **104** at a specific, predetermined angle. In effect, locking handle **111** into the first position would, for example, deflect the tip 30°. The next position would, for example, deflect the tip 60°. This feature would give the user even more control when positioning distal end **104** within the anatomy. In both cases, as finger rings **118** are actuated along body section **117**, and distal end **104** is bowed, the friction between the mating components would hold the position of handle **111**, and thus hold the position of the bow.

FIGS. **17-20** show various configurations of an alternate embodiment of the present invention for maintaining the position of an endoscopic instrument. In each of these configurations, the actuation of various handle assemblies has been modified to include an insert which provides a minimal amount of resistance. The resistance added to each of these configurations resists movement of the device away from a set or desired position. Each of the embodiments adds friction to the handles by means of placing a frictional element which provides interference between the moving parts. The interference provides a light braking force which resists movement in the distal end of a device without user intervention when the device is actuated by means of a handle. Each of the embodiments includes a frictional element composed of rubber, silicone, or other suitable material which provides the desired braking force. The minimal interference of the frictional element ensures that the interference does not prevent the continuous smooth movement of the handle actuators present during normal operation of the handle. In a preferred embodiment of the invention, the frictional elements described resist undesired movement in the distal end without requiring the user to engage, set or actuate a locking mechanism.

FIG. **17** shows a handle **1701** of a Rapid Exchange Tome. Attached to handle **1701** is thumb ring **116**. In operation, handle **1701** slides within body section **117** (not shown). Typically, a post or internal feature of body section **117** (not shown) translates within handle cutout **1702**. Insert **1703** resides within handle cutout **1702** and preferably protrudes outwardly from handle **1701**. The portion of insert **1703** which protrudes out of handle **1701** preferably makes contact with body section **117** and resists motion of body section **117** with respect to handle **1701**. One of ordinary skill would appreciate that both the composition of insert **1703** and the distance insert **1703** protrudes out of handle **1701** are factors in the amount of resistance felt in moving body section **117** with respect to handle **1701**.

FIG. **18** shows a "D" connector **1801** of an Ultratome. The incorporation of inserts at position **1802** and **1803** are used to resist movement of items, such as surgical instrument passing through the inserts.

FIGS. **19**A and B show two different embodiments of a soft brake for a Tome Handle. In both configurations, wire **1901**, such as a guidewire, passes through a D-connector **1902**. D-connector **1902** may be modified as shown to include an insert or stopper. FIG. **19**A shows a rubber stopper **1903** which spans the height of D-connector **1902**. As one of ordinary skill in the art would appreciate, wire **1901** enters D-connector **1902** at wire entrance **1908**. Wire **1901** then passes through first section **1904** of D-connector **1902**. Next, wire **1901** passes through first interface **1905** between D-connector **1902** and insert **1903**. Wire **1901** then passes through insert **1903**. Similarly, once wire **1901** exits insert **1903**, wire **1901** passes through second interface **1906** and a wider section **1907** of D-connector **1902**. The passage of wire **1901** through insert **1903** resists movement of wire **1901**. FIG. **19**B shows a similar configuration of insert **1904**, except that insert **1904** is included in only a section of the vertical portion of D-connector **1902**. One of ordinary skill in the art would appreciate that wire **1901** must pass through a section of insert **1904** to allow insert **1904** to resist movement in wire **1901**.

FIG. **20** shows another embodiment of the soft brake of the present invention. In this embodiment, wire **2001** passes through bushing **2002** held within handle **2003**. In this configuration, the circumferential friction applied to wire **2001** from bushing **2002** will resist wire **2001** movement.

FIGS. **21** through **23** show an alternate embodiment of the present invention in which a Tome-Loc handle design allows for the precise positioning and maintenance of the bow angle of a sphincterotome, or similar device, during the cutting procedure. This embodiment may be used to reduce or eliminate set relaxation. The design uses evenly spaced detents **2101** (FIG. **21**) machined, or otherwise formed, in handle body **111** that capture a raised bump or pawl **2202** (FIG. **22**) in the active cord insert **2201** (FIG. **22**) and hold pawl **2202** or sprag in place. One of ordinary skill in the art would appreciate that detents **2101** may be also be molded into handle body **111**. Detents **2101** may also be combined with graduation marks **2102** on the outside of handle body **111** to visually aid bow positioning. The modulus of elasticity of handle **111** acts as a spring to contain pawl **2202**. When the device is actuated, handle body **111** flexes out and allows pawl **2202** to move on to the next detent with some slight resistance or a click. The interaction between detent **2101** and pawls **2202** would allow the lock to be automatic without requiring additional buttons or levers to be articulated by the user and may be implemented to maintain a predictable feel without introducing difficulty in the manipulation of the device. FIG. **23** shows an interaction of detents **2101** with pawl **2202**. One of ordinary skill in the art would appreciate that the placement of detents **2101** on handle body **111** and pawls **2202** on active cord insert **2201** could be reversed in that detents could be placed on active cord insert (not shown) and pawls on handle body **111** (not shown). One of ordinary skill in the art would also appreciate that pawl **2202** need not necessarily be a hemispherical design but could also be a bar type or any type of configuration which would resist movement and locate into holes in handle body **111** to facilitate the detent feature. The basic design would rely on the same principals previously described.

FIG. **24** is a perspective view of an illustrative locking device **2401** for use with an endoscope having a side instrument port. The illustrative locking device is generally shown at **2401** and includes a body member **2402**. At one end, body member **2402** includes one or more hook members **2403** for attaching locking device **2401** to a shaft of an endoscope or the like (see FIG. **25**). At the other end, body member **2402** includes a securing mechanism for securing a guide wire or catheter to locking device **2401**. Hook members **2403** may be provided in pairs, as shown in FIG. **24**, or offset from one another, as shown in FIG. **27**. In either case, hook members **2403** are adapted to clip and secure locking device **2401** to the shaft of an endoscope or the like. The securing mechanism preferably includes one or more openings provided in body member **2402**. In the embodiment shown, body member **2402** includes a guide wire opening **2404** and catheter opening **2405**. Guide wire opening **2404** is preferably J-shaped, and preferably includes entry slot **2406** and locking slot **2407**. Catheter opening **2405** is boot shaped, and also preferably includes entry slot **2408** and locking slot **2409**.

Entry slot **2406** of guide wire opening **2404** is dimensioned to be larger than the diameter of a guide wire. Locking slot **2407** of guide wire opening **2404** is dimensioned to be somewhat smaller than the diameter of a guide wire. Accordingly, a guide wire can be secured to body member **2402** by inserting a portion of the guide wire through entry slot **2406** of guide wire opening **2404** and into locking slot **2407**. Locking slot **2407** frictionally secures the guide wire relative to body member **2402**. Likewise, entry slot **2408** of catheter opening **2405** is dimensioned to be larger than the diameter of a catheter. Locking slot **2409** of catheter opening **2405** is dimensioned to be somewhat smaller than the diameter of a catheter. Accordingly, a catheter can be secured to body member **2402** by inserting a portion of the catheter through entry end **2408** of catheter opening **2405** and into locking slot **2409**. Locking slot **2409** frictionally secures the catheter relative to body member **2402**.

FIG. **25** is a partial side view of an illustrative locking device positioned on an endoscope with an angled side port extending therefrom. The endoscope is generally shown at **2501**, and includes main shaft **2502** with a lumen extending therethrough. Side port **2503** extends laterally away from main shaft **2502** at an angle. Side port **2503** provides access to the lumen of main shaft **2502**. Accordingly, a guide wire and/or catheter may access the lumen of main shaft **2502** via side port **2503**. Side port **2502** preferably includes side port opening **2504** which is laterally spaced from main shaft **2502** due to the angular displacement between main shaft **2502** and side port **2503**. Side port opening **2504** is in fluid communication with the lumen of main shaft **2502** via connection tube **2505**. Connection tube **2505** intersects a side wall of main shaft **2502** at an angle, as shown.

A locking device having body member **2506** is shown clipped onto main shaft **2502** of endoscope **2501**. Body member **2506** includes a number of hook members **2507** for attaching the locking device to main shaft **2502**. Two hook members are visible in FIG. **25**. Hook members **2507** are similar to hook members **2403** described above with respect to FIG. **24**. Body member **2506** extends away from hook members **2507** and generally parallel to side port **2503**. In FIG. **25**, body member **2506** is obscured by main shaft **2502** and side port **2503**. Body member **2506** extends upward past side port opening **2504**, wherein a securing mechanism is provided. Preferably, the securing mechanism is a J-shaped guide wire opening **2508**. As seen in FIG. **25**, although partially obscured by main shaft **2502** and side port **2503** of endoscope **2501**, the attachment means comprising hook members **2507** is connected to the distal end of the body member **2506** and the securing means comprising the locking slot of the guidewire opening **2508** is connected to the proximal end of body member **2506** such that attachment means such as hook members **2507** are disposed distal of side port opening **2504** and securing are positioned proximal of side port opening **2504**.

In use, a guide wire is advanced into the body via the endoscope. During the advancement of the guide wire, the proximal end thereof may be moved to first position **2509**, which is in the entry slot of guide wire opening **2508**. Once the guide wire is in a desired position within the body, the guide wire may be moved to second position **2510**, which is in the locking slot of guide wire opening **2508**. The locking slot of guide wire opening **2508** frictionally secures the guide wire relative to body member **2506**.

FIG. **26** is a partial side view detailing the illustrative locking device of FIG. **25**, with an additional oversized catheter opening shown. The side port of the endoscope is shown at **2503**, and the body member of the locking device is shown at **2506**. Positioned proximate side port opening **2504** is guide wire opening **2508** and oversized catheter opening **2601**. Like above, the guide wire opening is J-shaped and includes an entry slot and a locking slot. Thus, the guide wire may be moved to first position **2509**, which is in the entry slot of guide wire opening **2508**. Once the guide wire is in a desired position within the body, the guide wire may be moved to second position **2510**, which is in the locking slot of guide wire

opening **2508**. The locking slot of guide wire opening **2508** frictionally secures the guide wire relative to body member **2506**.

Oversized catheter opening **2601** is sized to restrict lateral movement of catheter **2602** but not longitudinal movement of catheter **2602**. Providing a guide wire opening that can secure the guide wire relative to body member **2506** and oversized catheter opening **2601** for only restricting lateral movement of catheter **2602** may be particularly useful in performing a catheter exchange procedure. For example, during a catheter exchange procedure, guide wire opening **2508** may maintain the position of the guide wire. The oversized catheter opening **2601** may separate the catheter from the guide wire, as the catheter is withdrawn. The first and second catheters should be single-operator exchange type catheters to provide access to the guide wire during the exchange.

FIG. **27** is a perspective view of another illustrative locking device. The embodiment shown in FIG. **27** is similar to the embodiment shown in FIG. **24**, but the hook members are laterally offset rather than aligned. For example, hook member **2701** is laterally offset from hook member **2702** by a distance "D". This configuration is another example of an attachment mechanism for attaching the body member to a catheter shaft.

FIG. **28** is a perspective view of yet another illustrative locking device. The locking device is generally shown at **2801**, and includes body member **2802** having attachment mechanism **2803** at one end and securing mechanism **2804** at the other. Attachment mechanism **2803** includes first hook member **2805** and second hook member **2806**. First hook member **2805** and second hook member **2806** are adapted to extend around a substantial portion of the shaft of an endoscope or the like. Thus, first hook member **2805** and second hook member **2806** may clip body member **2802** to the desired shaft.

Securing mechanism **2804** includes J-shaped guide wire opening **2807** and flap-type catheter opening **2808**. J-shaped guide wire opening **2807** operates similar to that described above. Flap-type catheter opening **2808** has flap **2809** formed by cutting catheter opening **2808** from body member **2802**. Flap **2809** is preferably curved to form channel **2810**, wherein end portion **2811** of channel **2810** loops back to near the surface of body member **2802**. In this configuration, a catheter or guide wire may be selectively provided in channel **2810**, which may bend flap **2809** away from body member **2802**. Accordingly, flap **2809** may provide force between the guide wire or catheter and body member **2802** to effectively secure the guide wire or catheter to body member **2802**.

FIG. **29** is a partial side view of yet another illustrative locking device **2901**. Locking device **2901** is positioned between side port **2902** and main shaft **2903** of endoscope **2904**. Locking device **2901** includes body member **2905** that is attached to main shaft **2903** using strap **2906**. Preferably, strap **2906** extends around the entire circumference of main shaft **2903**. Further, body member **2905** may include guide wire opening **2907** and one or more catheter openings **2908**, as shown.

As previously described, the present invention relates to apparatus and methods used in positioning and maintaining the position of devices used in catheter procedures within the human anatomy. The present invention includes steerable devices, locking mechanisms and rapid exchange technologies to minimize or eliminate movement of endoscopic instruments during endoscopic procedures. Rapid exchange technologies may be included in the current invention to minimize movement of the devices when a guidewire is removed or a catheter is removed or exchanged.

FIG. **30** shows a partial elevational view of catheter assembly **3009** in accordance with the present invention. Catheter assembly **3009** is used in catheter procedures for accessing targeted anatomical regions through the alimentary canal. The present invention incorporates features which allow rapid exchange of catheter by a single operator. The catheter of the present invention allows shorter length guidewires to be used, resulting in procedures which require less medical personnel, are less time consuming, and less costly. Additionally, the present invention is adaptable to most catheter devices used for catheter procedures within the alimentary canal.

Catheter assembly **3009** includes catheter **3000** having guidewire **3010** passing through a portion thereof. Catheter **3000** includes shaft **3001** having proximal end **103** and distal end **104**. Operably connected to proximal end **103** of shaft **3001** is catheter hub assembly **122**. Catheter hub assembly **122** couples to ancillary devices allowing access to a lumen within shaft **3001**. Shaft **3001** is preferably formed in an extrusion process. Shaft **3001** may be formed of an extruded polymeric material. In one embodiment, the preferred polymeric material is polytetrafluoroethylene, polyether block amide, nylon or a combination or blend of these. Catheters which are contemplated include, but are not limited to, cannulas, sphincterotomes, cytology devices, and devices for stone retrieval and stent placement.

Shaft **3001** is a generally tubular shaped member having a generally uniform outer shape at its proximal end. Shaft **3001** may be sized for slidable passage through the lumen of an endoscope. Shaft **3001** includes distal taper **3002** which tapers to distal portion **105**. Distal portion **105** may include high contrast, color coded distal markers **3003**, and radiopaque distal tip **3004** for fluoroscopic visualization of distal portion **105** during a catheter procedure.

Shaft **3001** further includes proximal port or opening **3005** located proximal of distal end **104**. Proximal opening **3005** allows access to shaft **3001** for passage of guidewire **3010** through shaft **3001**. FIG. **30**A is a cross-sectional view of shaft **3001** taken along line **30**A-**30**A at a location proximal of proximal opening **3005**. Proximal to proximal opening **3005**, guidewire **3010** is positioned adjacent catheter shaft **3001**.

Extending longitudinally between the shaft proximal end **103** and distal end **104** is an ancillary lumen **3006** and a second ancillary lumen **3007**. Ancillary lumen **3006** and ancillary lumen **3007** may be injection lumens, allowing for high contrast media flow capability for bubble-free opacification and for excellent visualization of a desired anatomical region. Additionally or alternatively, ancillary lumen **3006** and/or ancillary lumen **3007** may be used for other ancillary devices, such as a cutting wire lumen or a retrieval balloon lumen.

Referring to FIG. **30**B, a cross-sectional view of shaft **3001** taken along line **30**B-**30**B of FIG. **30** is shown. Guidewire lumen **3008** extends between proximal opening **3005** and distal end **104**. Guidewire **3010** may enter guidewire lumen **3008** at proximal opening **3005**. Guidewire lumen **3008** is sized for slidable receipt and passage of guidewire **3010** through guidewire lumen **3008**. Referring to FIG. **30**C, guidewire lumen **3008** extends through distal taper **3002** and distal portion **105**. Guidewire lumen **3008** may also extend from distal end guidewire **104**.

Although it is recognized that proximal opening **3005** may be located at any location distal of proximal end **103**, proximal opening **3005** is preferably located less than 25 cm from distal end **104**. Guidewire lumen **3008** is a tubular member which is carried adjacent shaft **3001** ancillary lumen **3006** and ancillary lumen **3007**. Guidewire lumen **3008** may be formed integral with shaft **3001**, or alternatively, guidewire lumen

3008 may be part of a separate tubular member which is coupled to shaft 3001 as shown in FIG. 30D.

Now referring to FIGS. 30E and 30F, an alternative embodiment of the catheter depicted in FIG. 30 is illustrated. Catheter shaft 3001 of FIG. 30E incorporates a proximal guidewire opening which, in conjunction with the catheter, forms a circular cross section which allows for easy insertion of the guidewire. As depicted in FIG. 30F, guidewire lumen 3008 can include a larger proximal opening which funnels down to the size of guidewire lumen 3008 which extends distal to the distal end of catheter shaft 3001.

Guidewire lumen 3008 allows rapid exchange of catheter 3000 when an alternative catheter is necessary during a procedure. Shorter length guidewires may be used since guidewire 3010 does not pass through proximal end 103 and catheter hub assembly 122, but rather enters catheter shaft 3001 at proximal opening 3005 located substantially distal from proximal end 103. The unique catheter construction in accordance with the present invention will reduce catheter therapeutic and diagnostic procedure time since catheter device exchanges may be performed relatively more easily and quickly by a single operator. Additional personnel and time associated with maintaining the placement of a conventional (approximately 400 cm) guidewire within the targeted anatomical region is eliminated, reducing the overall costs of the procedure.

Referring to FIG. 31, a partial elevational view of a distal portion of catheter shaft 3001 is shown. Shaft 3001 may further include weakened area 3101. Weakened area 3101 extends longitudinally along guidewire lumen 3008 (not shown) between proximal opening 3005 and distal end 104.

When guidewire 3010 is positioned within guidewire lumen 3008, weakened area 3101 allows guidewire 3010 to be removed from guidewire lumen 3008 by "peeling away" guidewire 3010 from catheter shaft 3001. Weakened area 3101 may include less catheter material than the remaining portion of catheter shaft 3001, or may be perforated, cut or slit.

At least two different embodiments of weakened area 3101 are possible. In a first embodiment, weakened area 3101 is formed, and a slit, perforation or cut is introduced along the length of weakened area 3101 on the outside of catheter 3002 along the side of catheter 3002 which contains guidewire lumen 3008. In this embodiment, when removal of catheter 3002 is desired, a "directed tear" is performed in which the tear in guidewire lumen 3008 (and catheter 3002) follow the slit, cut or perforation. In a second embodiment, weakened area 3101 is formed by extruding catheter 3002 in a manner which creates sidewalls of catheter 3002 thin enough to be torn without requiring slits, cuts or perforations to be introduced after the catheter is extruded. In this embodiment, when catheter 3002 is to be removed, a non-directional tear occurs in the outside wall of guidewire lumen 3008. One of ordinary skill in the art would appreciate that the thin wall approach would reduce manufacturing costs and ensure catheters are single use items. The thin wall configuration may also be configured after extrusion such as by stretching the catheter, molding, or similar procedures.

Another embodiment of the present invention is shown generally in FIG. 32. FIG. 32 is a partial elevational view of catheter 3000, which may be a "convertible" catheter design. In catheter 3000, shaft 3001 includes opening 3005 which is skive port 3201 for access to guidewire lumen 3008. Catheter 3000 is a convertible catheter design in that an existing catheter may be modified to include skive port 3201. As a convertible catheter design, skive port 3201 is formed by cutting an opening in shaft 3001 for access to guidewire lumen 3008. It is recognized that catheter 3000 may be manufactured to include skive port 3201.

Referring to FIG. 32A, proximal to skive port 3201 catheter shaft 3001 includes ancillary lumen 3006 and ancillary lumen 3007 as previously described herein. Additionally, shaft 3001 includes guidewire lumen 3008 extending between proximal end 103 and distal end 104, including between skive port 3201 and proximal end 103. Referring to FIG. 32B, guidewire 3010 may access guidewire lumen 3008 at skive port 3201 and extend through guidewire lumen 3008, emerging from distal end 104.

With this embodiment, conventional guidewire techniques may be used for positioning and exchanging catheter 3000 within a patient's alimentary canal system. Further, the convertible catheter design incorporates features which allow rapid exchange of catheters by a single operator. Skive port 3201 opening 3005 allows catheter 3000 to be used in rapid exchange of catheter 3000 when an alternative catheter is necessary during a procedure. By allowing guidewire 3010 to enter guidewire lumen 3008 a location distal from proximal end 103, relatively shorter guidewires may be used during catheter procedures within the alimentary canal system, resulting in a more efficient and less costly procedure.

It is recognized that other means for accessing guidewire lumen 3008 at a location distal from proximal end 103 are contemplated within the scope of the present invention. Referring to FIG. 33, a weakened location or slit 3301 is shown within area A for accessing guidewire lumen 3008. Referring to FIG. 33A, proximal to slit 3301, guidewire 3010 may be positioned adjacent catheter shaft 3001. Guidewire 3010 enters guidewire lumen 3008 at slit 3301 for passage of guidewire 3010 through guidewire lumen 3008. Referring to FIG. 33B, guidewire 3010 is slidably contained within guidewire lumen 3008 at a location distal of slit 3301. With this embodiment, since guidewire lumen 3008 may extend longitudinally from proximal end 103 to distal end 104, conventional guidewire techniques may also be used during the catheter procedure.

Referring to FIG. 34, another embodiment of the catheter of the present invention incorporating features which allow rapid exchange of catheters by a single operator is generally shown. Catheter assembly 3004 includes a "port and channel" configuration. For access to guidewire lumen 3008, shaft 3005 includes a first opening or intermediate port 3401 located proximal of distal end 104. A second opening or proximal port 3402 is located proximal of intermediate port 3401 and proximal of distal end 104. Extending between intermediate port 3401 and proximal port 3402 is longitudinal channel 3403.

Guidewire lumen 3008 extends longitudinally between proximal end 103 and distal end 104. Referring to FIG. 34A, channel 3403 is located within the wall of catheter shaft 3405, providing access to guidewire lumen 3008 between proximal port 3402 and intermediate port 3401. Preferably, channel 3403 includes a radial opening extending between proximal port 3402 and intermediate port 3401. It is also recognized that channel 3403 may be a weakened area within the wall of the catheter shaft, a perforated area, or a slit which extends between proximal port 3402 and intermediate port 3401. Channel 3403 may also be included by manufacturing catheter 3405 with thinner exterior walls.

In one embodiment, intermediate port 3401 is located near distal end 104, and proximal port 3402 is located near proximal end 103. Referring to FIG. 35, distal end 104 of guidewire 3010 may be inserted within intermediate port 3401 (not shown), passing through guidewire lumen 3008, and emerg-

ing from catheter **3000** distal end **104**. Referring also to FIG. **35**A, guidewire **3010** may then be snapped through channel **3403** into guidewire lumen **3008** with the proximal end of guidewire **3010** exiting proximal port **3402**. With this "port and channel" design, both conventional and rapid exchange techniques may be used.

FIG. **36** shows a cut away diagram of an embodiment of the current invention which incorporates the rotating handle **111**, locking mechanism **3601** and rapid exchange technology into catheter **3602**. In FIG. **36**, cutting wire **113** is attached to handle **111** as described with respect to FIGS. **8** and **8**A. As handle **111** is rotated, distal end (not shown) of cutting wire **113** is also rotated to position a cutting portion (not shown) of cutting wire **113** in a desired orientation. Clicks or other audible indications may also be incorporated into catheter **3602** to indicate an amount of rotation accepted by handle **111** to an operator. A rotation lock as described in FIGS. **10-14**D may also be incorporated into catheter **3602**. The outside of bifurcation connector and body section **117** may also include a rotation marker. Guidewire **3010** may enter guidewire lumen **3008** through a proximal port or opening, as described with respect to FIGS. **30-33**B, or through a skive port as described in FIGS. **34-35**A. Guidewire **3010** may be removed from catheter **3601** through a slit, perforation, cut, or thinned wall of catheter **3602** as described with respect to FIGS. **30-31**. This procedure may permit the placement of a second catheter over the proximal end of a guidewire and proximal to the first catheter to allow rapid introduction of the second catheter once the first catheter is torn away.

FIG. **37** shows a non-directional tear in a thinned-wall catheter **3602**. When it is desired to separate catheter **3602** from guidewire **3010**, a force is exerted on guidewire **3010** in a direction away from catheter **3602**, or on catheter **3602** in a direction away from guidewire **3010** which causes catheter **3602** to tear **3701** in a non-directional manner. One of ordinary skill in the art would appreciate from FIG. **37** that catheter **3602** above point **3703** where guidewire **3010** contacts catheter **3602** has not been perforated, cut or slit as indicated near reference number **3702**. As additional pressure is exerted on guidewire **3010** or catheter **3602**, tear **3701** will continue toward distal end **104**.

FIG. **38** shows catheter **3602** positioned through endoscope **3801** detailing the relationship of the guidewire and the catheter when a rapid exchange catheter is used. When a catheter exchange is required or desired, the position of guidewire **3010** may be maintained by withdrawing catheter **3602** from the patient and tearing catheter **3602** from guidewire **3010**.

FIG. **38**A is a sectional view along line **38**A-**38**A of FIG. **38**. As catheter **3801** is torn from guidewire **3010**, a portion of the thinned wall of catheter **3801** is torn in a non-directional manner **3802**. One of ordinary skill in the art would appreciate that by introducing slits, cuts or perforations into catheter **3801**, a directional tear may be assured.

While the present invention is described in terms of a catheter used in accessing the biliary tree, one of ordinary skill in the art would appreciate that the present invention includes the introduction of an endoscopic instrument into any body lumen. In other embodiments, the present invention may be used to position and maintain the orientation of an endoscopic instrument within any body lumen. For example, the present invention may be incorporated into a catheter for use in, but not limited to, the pulmonary system, vascular ducts, or urino-genital procedures.

What is claimed is:

1. An apparatus for the accurate positioning of endoscopic instruments, comprising:

an elongate catheter shaft having a proximal portion, a distal portion, an outer surface, and a lumen formed therein;

a handle coupled to the proximal portion of the catheter shaft;

a cutting wire having a first portion attached to the distal portion of the catheter shaft, a second portion disposed along the outer surface of the catheter shaft, and a third portion attached to the handle;

wherein the handle is coupled to the catheter shaft with a rotatable coupling that allows the handle to rotate independently of the catheter shaft;

a locking mechanism that, when engaged, prevents lengthwise movement of the cutting wire; and

a rotating indicator that is configured to indicate the amount of rotation of the handle relative to the catheter shaft

wherein the rotating indicator includes an audible indicator.

2. The apparatus of claim **1**, wherein the locking mechanism includes a friction lock within the handle.

3. The apparatus of claim **1**, wherein the locking mechanism includes a friction engagement between the handle and the third portion of the cutting wire.

4. The apparatus of claim **1**, wherein the locking mechanism includes one or more locking ribs configured to hold the distal portion of the elongate catheter at a specific, predetermined angle.

5. The apparatus of claim **4**, wherein a first locking rib holds the distal portion at a 30 degree angle relative to a straight configuration of the elongate catheter.

6. The apparatus of claim **5**, wherein a second locking rib holds the distal portion at a 60 degree angle relative to a straight configuration of the elongate catheter.

7. The apparatus of claim **1**, wherein the rotation indicator further includes a visual indicator.

8. The apparatus of claim **1**, wherein the distal portion of the catheter shaft has a first outer diameter and wherein the proximal portion of the catheter shaft has a second outer diameter greater than the first outer diameter.

9. The apparatus of claim **1**, wherein the catheter shaft has two or more lumens formed therein.

10. The apparatus of claim **9**, wherein the catheter shaft has three lumens formed therein.

11. A medical device, comprising:

an elongate catheter shaft having a proximal portion, a distal portion, an outer surface, and a lumen formed therein;

a handle coupled to the proximal portion of the catheter shaft;

a cutting wire having a first portion attached to the distal portion of the catheter shaft, a second portion disposed along the outer surface of the catheter shaft, and a third portion extending through the lumen and being attached to the handle;

wherein the handle is coupled to the catheter shaft with a rotatable coupling that allows the handle and the cutting wire to rotate independently of the catheter shaft;

a rotation lock for preventing rotation of the catheter shaft relative to the handle; and

a locking mechanism configured to hold the distal portion of the catheter shaft at a specific, predetermined angle with respect to the proximal portion of the catheter shaft;

wherein the rotation lock includes a first pair of detents and the handle includes a second pair of detents configured to mate with the first pair of detents.

12. The medical device of claim **11**, wherein the distal portion of the catheter shaft is actuated to various angles relative to the proximal portion of the catheter shaft via lengthwise movement of the cutting wire.

13. The medical device of claim **12**, wherein the locking mechanism includes a friction engagement between the handle and the third portion of the cutting wire.

14. The medical device of claim **11**, further comprising a rotation indicator that is configured to indicate the amount of rotation of the handle relative to the catheter shaft.

15. The medical device of claim **11**, wherein the handle includes a brake configured to resist movement of a guidewire within the catheter shaft.

16. A medical device, comprising:

an elongate catheter shaft having a proximal portion, a distal portion, an outer surface, and a lumen formed therein;

a handle coupled to the proximal portion of the catheter shaft

a cutting wire having a first portion attached to the distal portion of the catheter shaft, a second portion disposed along the outer surface of the catheter shaft, and a third portion extending through the lumen and being attached to the handle;

wherein the handle is coupled to the catheter shaft with a rotatable coupling that allows the handle and the cutting wire to rotate independently of the catheter shaft

a rotation lock for preventing rotation of the catheter shaft relative to the handle; and

a locking mechanism configured to hold the distal portion of the catheter shaft at a specific, predetermined angle with respect to the proximal portion of the catheter shaft;

wherein the rotation lock is a friction lock that includes a post that frictionally engages the handle, the post including an oval post, a triangular post, or a square post.

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